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(71) Applicant: THE KENDALL COMPANY
One Federal Street
Boston Massachusetts 02110-2003(US)

(72) Inventor: Dye, John F.
332 Vincent Place
Elgin, Illinois 60120(US)

(74) Representative: Kearney, Kevin David Nicholas et al
KILBURN & STRODE 30 John Street
London, WC1N 2DD(GB)

(54) Full length compressible sleeve.

(57) A sleeve for applying compressive pressures against a patient's limb from a source of pressurized fluid, wherein the sleeve comprises a multi-layered sheath, having a proximal and a distal end. Generally parallel side edges extend between the proximal and distal ends, which side edges, on the proximal half of the sheath, are adjustably wrappable about the patient's limb, once it is inserted in the sleeve.

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FULL LENGTH COMPRESSIBLE SLEEVE

This invention relates to pressurizable, multi-chambered, therapeutic devices, and more particularly to sleeves for applying compressive pressures against a patient's leg.

Blood flow in patient's extremities, particularly the legs, markedly decrease during extended terms of confinement. Such pooling or stasis, is particularly acute in surgery and during recovery periods immediately thereafter.

Blood flow compressive devices, such as shown in U.S. Patents 4,013,069 and 4,030,488, incorporated herein by reference, develop and facilitate the application of compressive pressures against a patient's limbs and in so doing promoting venous return. The devices comprise a pair of sleeves which are wrapped about the patient's limbs, with a controller for supplying the pressurized fluid to the sleeves.

These sleeve devices may be seen in U.S. Patents 4,402,312 and 4,320,746, which are also incorporated herein by reference.

One use for the above mentioned sleeves is the prevention of deep vein thrombosis (DVT) which sometimes occurs in surgical patients who are confined to bed. When a DVT occurs, the valves that are located within the veins of the leg can be damaged which in turn can cause stasis and high pressure in the veins of the lower leg. Patients who have this condition often have leg swelling (edema) and tissue breakdown (venous stasis ulcer) in the lower leg.

It has been shown that pneumatic compression can be highly effective in the treatment of such edema and venous ulcers. This treatment is usually performed by the patient themselves at home on a daily basis and requires that the patient be able to put on and remove the sleeves unassisted. The sleeve devices which are wrappable from a flat configuration as shown in the aforementioned patents, are difficult to apply by the patients themselves.

It is therefore an object of the present invention, to provide a compressible sleeve device which is easily utilizable at home by the patient himself.

A further object of the present invention is to optimize therapy for venous ulcers and edema associated with poor venous return.

According to the present invention a sleeve for applying compressive pressures against a patient's limb from a source of pressurized fluid comprises an elongated sheath preferably multi layered defining a plurality of compressive chambers which may be generally limb encircling, the said sheath having an open proximal end and a closed distal end, the said sheath being adapted to receive a patient's limb through its open proximal end; the said sheath having a front portion for juxtaposition with the front surface of a patient's limb, and a back portion for juxtaposition with the back surface of a patient's limb; the said front and back portions of the said sheath carrying mutual engagement means and being adapted to be wrapped over each other to permit engagement of the mutual engaging means, permitting girthwise adjustment of the said sleeve about a patient's limb, for example the front and back portions of the sheath having transversely extending side elements, the said side elements having a gripping edge thereon and the said front portion having gripping means thereon, the said side elements being wrappable over and securable to the said front portion of the sheath.

The said front portion and the said back portion of the said sheath are preferably joined along their common edges coinciding between the said proximal end and the said distal end, to define the said sheath.

The said front portion and the said rear portion preferably have a common coinciding edge only partway along the length of the side of the said sheath from the said proximal end to the said distal end, to permit openability of the said sheath, thus facilitating entry of a patient's limb into the sheath.

The said back preferably includes a cushion pad for the juxtaposition of a patient's foot thereagainst.

A compressive chamber is preferably disposed in the said back portion of the said sheath, about the said foot cushion pad.

A compressive chamber is preferably longitudinally disposed in the said front portion of the said sheath, extending from the distal end thereof, to or towards the proximal end thereof, said compressive chamber about the said foot cushion pad and the said longitudinally disposed compressive chamber in the said front portion are preferably in fluid communication with one another.

The sleeve preferably includes a plurality of compressive chambers extending transversely across the said back portion of the said sheath so as to extend around the fleshy portions of a leg when the sheath is wrapped therearound.

The chambers preferably extend across the back portion of the said sheath including the said side elements. Thus they may generally encircle a limb placed in the said sheath.

Indicia, e.g. a centre line, are preferably disposed longitudinally along, e.g. the middle of said gripping means, the front portion to assist a patient in properly aligning the said sleeve on his limb. The sheath is preferably a multi-layered sheath and

comprises an innermost film of flexible extensible plastic, and an outermost sheet of flexible material, preferably less extensible, which between them define the said compressive chambers. The sleeve preferably includes a plurality of conduits to duct pressure fluid e.g. air from a pressure source to the said compressive chambers, at least one of the said conduits preferably ducting the said air to more than one of the said compressive chambers. The sheath preferably comprises an outer sheet which is relatively stiff and inelastic so that it remains relatively flat upon inflation on introduction of pressure fluid within the said compressive chambers; and an inner sheet which is soft and compliant, so that upon inflation the said inner sheet conforms substantially to the shape of the said limb.

In a preferred form of the invention the said front portion is adapted for placement against the bony front of a patient's leg, the said front portion being substantially inelastic, whereby when compression occurs by introducing the said fluid within the said chambers, tension is applied across the curvature of the said front portion, which tension translates into a pressure over the radius of curvature along the front of the said leg.

In this preferred form of the invention the said inelastic front portion and the said back portion of the said sheath when secured to enclose a patient's leg provide pressure chamber means for filling the hollow portions at either side of the said bony portion of the leg, whereby tension on the said inelastic front portion will result in compression at that portion of the leg.

The said pressure chamber means in the said front portion is preferably partially bifurcated. The bifurcation of the front portion chamber has the advantage of avoiding any pressurizable chamber along the mid portion of the front portion of said proximal end of the said sheath.

Desirably the sleeve is provided with a portion adapted to enclose a patient's foot when the said front and back portions are wrapped over and secured together, the said foot portion in juxtaposition with the bottom of the said patient's foot containing no compressive chamber and thereby being non-inflatable.

Preferably the said portion enclosing the said foot contains cushion means for the bottom of the said foot.

The invention also extends to a method of applying sequentially variable compressive pressures, in addition to a constant base pressure, against a patient's limb, from a source of pressurized fluid comprising providing a multi-layered elongated sheath around the limb, the sheath defining a plurality of generally limb encircling compressive chambers having an open proximal end and a closed distal end, the said sheath receiving the patient's limb through its open proximal end; the said sheath also having a chambered front portion for juxtaposition with the front surface of a patient's limb, and having a chambered back portion for juxtaposition with the back surface of a patient's limb; the said sheath also having a generally oval shaped pad arranged near the distal end thereof, with a compressible chamber disposed about the periphery of the said pad; the said front portion chamber and said peripherally disposed compressible chamber being maintained at a constant base pressure therein while the said generally limb encircling compressive chambers are pressurized sequentially.

Preferably the said front portion chamber and the said peripherally disposed compressible chamber are in fluid communication with one another.

The various forms of sleeve described above are advantageously utilized in carrying out the method of the invention.

The invention in a further aspect affords an elongated compressible sleeve device adapted for enclosing a length of an individual's limb and for applying compressive pressure thereto, the said device including inner and outer sheet materials sealed together to define a plurality of pressurizable chambers, the said device further including inlet means for introducing a fluid to inflate the said chambers, whereby to apply the said compressive pressure against the said enclosed limb; having the improvement wherein the said outer sheet is relatively stiff and inelastic whereby it remains relatively flat upon inflation by introducing the said fluid within said chambers, and the said inner sheet is soft and compliant whereby upon inflation the said inner sheet conforms substantially to the shape of the said enclosed limb.

The present invention provides an elongated compressible sleeve device for enclosing a length of a patient's limb, the sleeve having a plurality of sets of adjoining laterally extending fluid pressure chambers.

The sleeve is preferably comprised of a single elongated outermost sheet of flexible fluid-impervious material such as urethane-coated nylon.

An "inner" film of a suitable flexible fluid-impervious material such as urethane is preferably disposed against the upper side of the "outer" elongated sheet, having common sealed peripheral margins. The film is preferably sealed with respect to the outer sheet to define a plurality of pressurizable chambers. The outer sheet is most preferably stiffer and inelastic or less elastic relative to the inner film, thereby permitting the inner layer to conform appreciably better to the shape of the leg. Thus, the outer sheet will remain relatively flat upon inflation while the inner film inflates and the

areas of the film defining adjacent chambers press together, which in turn substantially inhibits zero pressure areas. The elongated sheet and attached film is preferably folded upon itself along a transverse fold near its longitudinal mid-point. The sheet is then preferably joined along all of one and a portion of its other longitudinal edges when folded upon itself to leave one side open from the midpoint upwardly for ease of inserting the limb, thereby forming a two-layered sheath-like structure, open at its proximal end to define an inner film and outer sheet arrangement. A plurality of conduits are preferably arranged in fluid communication with their respective chambers, each conduit preferably terminating in a connector adjacent the open end of the sleeve.

The sleeve has a distal end which is preferably closed by its transverse fold, for the enclosed emplacement of a patient's foot. An oblong or generally oval non-inflatable pad is preferably enclosed between the inner and outer sheets at the distal end of the sleeve, on top of the film, to provide a cushion base for the patient's foot.

The outer film of the topmost layer is arranged to be positionable over the front side of a patient's limb. An adhering or securement means is preferably disposed along the front of the topmost layer.

The side edges of the topmost layer, from the proximal end of the foot chamber, to the uppermost end of the sleeve, preferably have an adhering strip attached therealong. The longitudinal side portions of the sleeve preferably include margins or flap portions which are foldable onto the adhering means, so as to adjustably encase the wearer's limb in the sleeve.

The topmost layer preferably comprises a pair of longitudinally directed pressurizable chambers which are in fluid communication with the pressurizable chamber above and alongside the patient's foot.

A longitudinally directed centrally disposed sight line may be arranged along the middle of the adhering means to permit the patient to line up the sleeve, so that the sight line is aligned up the middle of the limb, permitting most effective utilization and location of the compressive chambers on the limb.

When the sleeve fully encloses a patient's limb, and the marginal side flaps of the sleeve are wrapped over and adhered to their respective sides of the adhering means, the patient's limb is almost completely surrounded by inflatable chambers, awaiting sequential pressurization. However, the front of a patient's leg is bony and hence requires no pressurizable chambers. The important area is the muscular area on the sides and back of a patient's leg, which contains the veins to which compressive pressure needs to be applied in accordance with this invention. The front side of the sleeve, which comprises the tongue portion thereof, is preferably inelastic, so that when compression occurs in the remainder of the sleeve and onto the leg, tension is applied across the curvature of the tonge which in effect translates into pressure over the radius of curvature along the front of a patient's leg.

The present invention in a further aspect also relates to an improved device for applying compressive pressures to a patient's limb, and an improved manner of controlling the pressure supplied to the sleeves..

The device according to this aspect comprises a sleeve for placement on a patient's limb, with the sleeve having a plurality of chambers arranged longitudinally along the sleeve, including a monitored chamber, means responsive to a control signal for forming a fluid under pressure, means for generating the control signal, means for selecting a predetermined value of the control signal by the generating means to select a desired predetermined pressure by the forming means, and means for connecting the fluid from the forming means to the chambers of the sleeve, including the monitored chamber.

A feature of this aspect of the invention is that the pressure of the monitored chamber is compared by comparing means with the desired predetermined pressure of the selecting means.

Another feature of this aspect of the invention is the provision of means responsive to the comparing means for modifying the control signal of the generating means to control the forming means to form the predetermined pressure.

Thus, a feature of this aspect of the invention is that predetermined pressure is formed in a simplified manner merely by selection of push buttons.

Another feature of this aspect of the invention is that the predetermined pressure is formed by electrical signals.

Yet another feature of this aspect of the invention is that the predetermined pressure is formed with increased precision.

The present invention in a further aspect is concerned with the provision of an improved connection device of simplified construction for connecting a source of fluid to the chambers in a plurality of sleeves.

A connection device in accordance with this aspect of the present invention preferably comprises an intermediate member having a pair of opposed first and second sides, and a plurality of spaced annular walls defining a plurality of separate annular channels extending substantially peripherally around the intermediate member, and first and second walls covering the opposed first and second sides of the intermediate member and

closing the channels of the intermediate member, with each of the walls having opening means extending therethrough and separately communicating with each of the channels of the intermediate member. The device according to this aspect preferably has a plurality of first conduits separately communicating with each of the channels of the intermediate member to permit passage of fluid to the channels. The device according to this aspect preferably has a first connector positioned adjacent the first wall and having a plurality of annular walls defining separate annular channels extending substantially peripherally around the first connector, with each of the channels of the first connector separately communicating with the opening means of the first wall such that the channels of the first connector separately communicate with the channels of the intermediate member, with the first connector preferably being rotatable with respect to the intermediate member. The device preferably has a plurality of second conduits separately communicating with each of the channels of the first connector to permit passage of fluid from the channels. The device preferably has a second connector positioned adjacent the second wall and having a plurality of annular walls defining separate annular channels extending substantially peripherally around the second connector, with each of the channels of the second connector separately communicating with the opening means of the second wall such that the channels of the second connector separately communicate with the channels of the intermediate member, with the second connector preferably being rotatable with respect to the intermediate member. The device preferably has a plurality of third conduits separately communicating with each of the channels of the second connector to permit passage of fluid from the channels. In a preferred form of this aspect of the invention the device has means for releasably retaining the first connector at a plurality of positions relative to the intermediate member, and preferably means for releasably retaining the second connector at a plurality of positions relative to the intermediate member.

An advantage of this aspect of the present invention is that the connector may be readily assembled and disassembled in order to connect or disconnect a sleeve which is attached to the first or second connector.

A further advantage is that the first and second connectors may be rotated to a desired position relative to the intermediate member and retained in place.

Preferably the first and second walls comprise elastic members in order to provide seals between the intermediate member and the first and second connectors.

The present invention in a further aspect relates to an improved device for applying compressive pressures against a patient's limb.

The device of this aspect of the present invention comprises a sleeve for applying pressure against a length of the patient's limb, with the sleeve having a plurality of chambers arranged longitudinally along the sleeve. The device preferably has means for intermittently inflating the chambers during periodic compression cycles. The device preferably has means for intermittently connecting the chambers to an exhaust means.

This aspect of the present invention preferably provides means for establishing a residual pressure in the chambers.

The residual pressure in the chambers is preferably established after chambers of the sleeve are connected to the exhaust means.

Preferably inflating means inflate the chambers to form a compressive pressure gradient which decreases from one position e.g. a lower portion of the sleeve to another portion e.g. an upper portion of the sleeve.

An advantage of this aspect of the present invention is that the residual pressure established in the chambers reduces the requirement for air for inflation of the chambers during the periodic compression cycles.

Another advantage of this aspect of the invention is that additional chambers, such as used for placement against the foot and knee, can be provided and maintained at the residual pressure.

Preferably the residual pressure remains substantially the same throughout use of the device.

Since residual pressure remains in the chambers of the sleeves when they are connected to the exhaust means, the chambers may be more readily inflated during subsequent compression cycles.

Another advantage of this aspect of the invention is that the device controls endothelial stretch or venous distension.

Another advantage of this aspect of the invention is that by preinflating the chambers of the sleeve to the residual pressure, the sleeves are much less sensitive to fit.

Another advantage of this aspect of the invention is that the residual or base line pressure makes the sleeve conform more readily to the limbs.

Another advantage of this aspect of the invention is that the performance required for a compressor to be suitable to be used in the device to inflate the sleeves is reduced, such that the compressor may be made smaller and less powerful.

Another advantage of this aspect of the invention is that in certain embodiments of the invention the sleeve may be designed to make it easier to apply since it is less sensitive to fit.

The invention in one embodiment of this aspect of the device may be utilized to treat venous ulcers and edema in the home.

In another embodiment of this aspect the device may be utilized for the control of deep venous thrombosis in hospital.

According to a first form of this aspect of the present invention a device for applying compressive pressures against a patient's limb, comprises a sleeve for applying pressure against a length of a patient's limb, the said sleeve having a plurality of chambers arranged longitudinally along the sleeve; means for intermittently inflating the said chambers during periodic compression cycles; and means for intermittently connecting the chambers to an exhaust means and for establishing a residual pressure in the chambers.

The inflating means preferably form a compressive pressure gradient in the said chambers which decreases from a lower portion of the sleeve to an upper portion of the sleeve.

The sleeve preferably includes at least one additional chamber. The establishing means preferably forms a base pressure in the said additional chamber.

The sleeve preferably includes a chamber for applying pressure against the foot. The establishing means preferably forms a base pressure in the foot chamber.

The sleeve also preferably includes a chamber for applying pressure against the knee. The establishing means preferably forms a base pressure in the knee chamber.

The inflating means preferably sequentially inflates the said chambers.

The connecting means preferably includes valve means for establishing the said residual pressure.

The valve means preferably includes means for adjusting the value of the residual pressure.

The sleeve preferably includes at least one additional chamber. The connecting means is preferably connected to the valve means and to the said additional chamber.

The valve means preferably comprises a valve member, a seat, and means for biasing the valve member against the seat.

The biasing means is preferably adjustable.

The connecting means preferably simultaneously connects the chambers to the exhaust means.

The connecting means preferably includes a plurality of valves to control the passage of fluid from the chambers to the exhaust means.

The inflating means preferably includes means for establishing a source of pressurized fluid, and means for sequentially connecting the source to the said chambers.

The valve means preferably comprises a first body portion having an annular wall defining a cavity, a second body portion having an annular wall and opening means, means for releasably securing said annular walls of the first and second body portions together, a valve seat in the cavity of the first body portion, a valve member extending from an outer portion of the second body portion, and means for biasing the valve member against the seat.

In a second form of this aspect the invention extends to a device for applying compressive pressures against a patient's limb, comprising a sleeve for applying pressure against a length of a patient's limb, the said sleeve having a plurality of chambers arranged longitudinally along the sleeve; means for establishing a base pressure in said chambers; and means for intermittently inflating the said chambers to a pressure greater than the said base pressure while forming a compressive pressure gradient which decreases from a lower portion of the sleeve to an upper portion of the sleeve.

In a third form of this aspect the invention extends to a device for applying compressive pressures against a patient's limb, comprising a sleeve for enclosing a length of a patient's limb, the said sleeve having a plurality of chambers arranged longitudinally along the sleeve; means for intermittently inflating said chambers during periodic compression cycles; and means for intermittently connecting the chambers to an exhaust means during periodic decompression cycles; and means for establishing a residual pressure in the chambers during the decompression cycles.

The establishing means preferably comprises valve means.

Alternatively, the establishing means may comprise a container retaining a quantity of liquid, and conduit means of the connecting means extending into the liquid.

In a fourth form of this aspect the present invention extends to a device for applying compressive pressures against a patient's limb, comprising accumulator means defining a cavity for retaining a volume of fluid; means for forming a source of pressurized fluid in the said accumulator means; a sleeve having a plurality of chambers arranged longitudinally along the sleeve; valve means for sequentially connecting the cavity to the said chambers while forming a compressive pressure gradient which decreases from a lower portion of the sleeve to an upper portion of the sleeve; pressure relief means to permit passage of fluid at a predetermined pressure; and means for selectively connecting the cavity to the pressure relief means to form the predetermined pressure in the accumulator means.

The valve means preferably permits passage

of fluid from the chambers to the cavity while the connecting means preferably permits passage of fluid from the cavity to the pressure relief means.

The connecting means preferably includes valve means for connecting the cavity to the pressure relief means.

The forming means preferably comprises a compressor.

The device preferably includes means for adjusting the predetermined pressure of the pressure relief means.

The pressure relief means preferably comprises valve means to permit passage of fluid therethrough. Alternatively the pressure relief means comprises a container retaining a quantity of liquid, and conduit means in fluid communication with the accumulator means and extending below an upper level of the liquid.

In a fifth form of this aspect the present invention extends to a device for applying compressive pressures against a patient's limb, comprising: a sleeve for applying pressure against a length of a patient's limb, the said sleeve having a plurality of chambers arranged longitudinally along the sleeve; means for intermittently inflating the said chambers during periodic compression cycles; and valve means for simultaneously connecting the chambers to an exhaust means and for establishing a residual pressure in the chambers.

The establishing means preferably comprises a pressure relief valve. The device preferably includes conduit means connecting the valve means to the exhaust means.

In a sixth form of this aspect the present invention extends to a device for applying compressive pressures against a patient's limb, comprising: a sleeve for applying pressure against a length of a patient's limb, the said sleeve having a plurality of compression chambers arranged longitudinally along the sleeve; means for intermittently inflating the said chambers during periodic compression cycles; chamber means defining a chamber enclosing the compression chambers; and means for forming a residual pressure in the chamber of said chambers means.

The chamber means preferably comprises elongated wall means enclosing the said compression chambers.

The invention may be put into practice in various ways and one specific embodiment will be described by way of example to illustrate the invention with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of a full limb length compressible sleeve constructed according to the principles of the present invention;

Figure 2 is another perspective view of the sleeve shown in Figure 1, with a patient's limb depicted therein;

Figure 3 is a plan view of the elongated outer sheet, which when folded generally along its transverse mid-point, comprises the outer layer of the sleeve;

Figure 4 is a plan view of an inner film disposed upon the outer sheet having the chambers defined by seal margins between the inner film and the outer sheet; and

Figure 5 is a plan view on an enlarged scale of the sleeve, with the inner and the outer sheet joined at their appropriate peripheral locations.

The present invention comprises an elongated compressible sleeve 10 for enclosing a patient's limb, and is of a form and shape appropriate for a leg. The sleeve 10, shown in perspective view in Figure 1, includes a plurality of adjoining generally transversely extending fluid pressurizable chambers 12, which are shown more clearly in Figure 4.

The sleeve 10 is comprised of an outermost flexible fluid-impervious sheet 14, made of urethane-coated nylon, or the like, in an elongated form, as shown in Figure 3. The outermost sheet 14 has a first end 16 and a second or opposed end 18, each of which has a transverse dimension that narrows (tapers) slightly to a general mid-point of the sheet 14, defined by a transverse fold line 20.

The sleeve 10 is also comprised of an innermost flexible fluid-impervious film 22, made of plastic material such as urethane, having a peripheral outline, as shown in Figure 4, which is generally similar to the configuration of the outermost sheet 14. As previously stated, the outermost sheet is stiffer and less elastic or inelastic relative to the innermost film so that the latter conforms well to the shape of the leg while the former remains relatively flat upon inflation.

The film 22 has a first end 24 and a second end 26, each of which has a transverse dimension that narrows slightly to a general mid-point of the film 22 defined by the common transverse "fold" line 20. The peripheral outline of the innermost film 22 is substantially the same as the periphery of the outermost sheet 14. Preferably, however, the length of the film 22, to the right of the common "fold" line 20 as shown in Figure 4, is shorter than the corresponding length of the outer sheet 14, e.g. of the order of 20% shorter.

In both the outermost sheet 14, and the innermost film 22, the longer portion of each to one side of their common fold line 20, comprises the backside portion 17 of the sleeve 10 having elongated side marginal portions 70 which wrap about the patient's limb from the backside thereat, which portions are to the left of the fold line 20, viewing Figure 2.

The innermost film 22 is placed over the outermost sheet 14, with their common fold line 20,

and their first ends 24 and 16 also contiguous, as shown in Figure 4. The section of the sleeve 10, to the right of the fold line 20, as shown in Figure 4, will comprise the frontside portion 19, of the sleeve 10, when the film 22 and sheet 14 are folded along the fold line 20, onto themselves, to form the sleeve.

The innermost film 22 may then be sealed to the outermost sheet 14 generally at the periphery 23 of the film 22 and at seal lines 32 which also define a plurality of longitudinally spaced transversely directed pressurizable chambers 12 between the innermost film 22 and the outermost sheet 14. The seal lines 32 and the chambers 12 are shown in Figure 4 prior to the folding of the elongated sheet 14 and the film 22 and subsequent peripheral joining. Suitable sealing means, e.g. radio frequency (RF) sealing means, will be readily suggested to those skilled in the art.

A foot pad 36, of generally oval shape, is non-pressurizably disposed between the sheet 14 and the film 22, to form a cushion against which a patient's foot is placed, as may be seen in Figure 2. A front pressurizable chamber 34, partially bifurcated, is disposed to the right of the fold line 20 of Figure 4. The front chamber 34 is in fluid communication with a chamber 35 which extends around the side portions of the foot pad 36. The bifurcated chamber 34 eliminates any pressure chamber juxtaposed against the very forwardmost bony part of a patient's leg, when it is enclosed in the sleeve 10. This in turn applies compression to the flat leg sections on either side of the forwardmost bony portion of the lower leg. Since these flat leg sections are the sites of many ulcers, it follows that they are important areas for applying compressive pressure in accordance with this invention. The backside portion 17 of the sleeve 10 includes a lowermost pressurizable ankle chamber 38, an intermediate calf chamber 40, a first thigh chamber 42 and an upper thigh chamber 44. Each chamber 38, 40, 42 and 44 has an orifice 46 for the supply of pressure fluid e.g. for the sequential pressurization and depressurization of those chambers, through a plurality of conduits 50, through a coupling adapter 51, which is in fluid communication through further conduits 53 with a compression generator. This arrangement may be as identified in various patents including those previously incorporated by reference herein. The chamber 35, disposed about the sides and forepart of the pad 36, as well as the pressurizable chamber 34 in the frontside of the sleeve 10, including the top of the foot, is preferably maintained at a constant base pressure of about 10 pounds pressure, from a pressure generating source as aforementioned.

The supply of fluid pressure may be controlled as described and claimed in our copending Application No. Serial No. (our case P15029EP) based on USSN 336979. This type of supply is described in more detail below.

The coupling adapter 51 may very desirably be of the type described and claimed in our copending Application No. Serial No. (our case P15025EP) based on USSN 337606. This type of adapter is described in more detail below.

The sequential pressuriation and depressurization mentioned above may be carried out as described and claimed in our copending Application No. Serial No. (our case P15026EP) based on USSN 336984. This type of pressurization is discussed in more detail below.

During assembly of the sleeve 10, the frontside 19 of the sleeve 10 is folded over onto the backside portion 17 of the sleeve 10, along their common fold line 20, and are joined, as by stitching or the like, along their common peripheral points, as indicated by "P", shown in Figure 5. The common peripheral points P may be recited as one generally longitudinally common side edge 52, and another side edge 54, only a portion of which is common to the frontside 19 and the backside 17. A longitudinal opening 56 extends almost half-way along one longitudinal side, and the sleeve 10 is open at its proximalmost end 60, to permit, in conjunction with the side opening 56, a patient to easily slide his leg "L" into the sheath-like arrangement of the sleeve 10.

A generally rectangular (slightly truncated) patch of receiving cloth 62 is secured to the outside upper portion of the frontside 19, of the sleeve, as shown in Figures 1, 2, 3, and 5. A narrow strip 64 of hook means, such as the trademarked "Velcro" material, is attached adjacent the elongated marginal side edges 70, as shown in Figures 1, 2, and 5.

After a patient has placed his leg or limb in the sheath-like sleeve 10, the longitudinal side portions along the proximal segment of the sleeve 10, may be wrapped about the patient's limb "L" as shown in Figure 2, so that the narrow strip 64 of hook means engages the receiving cloth 62 to encircle the patient's limb and hold the sleeve closely around the leg. A marker (or sight) line "M" as shown in Figure 1, may be disposed on the topside of the receiving cloth 62, to facilitate alignment of the sleeve with the front midportion of the patient's limb (leg). The sheath shown in Figure 5 is of a size such as to reach just above the knee. Longer sheaths may be used.

Air or other pressurizable fluid may then be directed through the conduits 46 into the chambers 34, 38, 40, 42 and 44 in the manner, e.g. of sequence and pressure profile, created by the pressure generator aforementioned. (One such arrangement is described below.)

In view of the foregoing description and illustrative drawings, it will thus be appreciated that the present invention provides a therapeutic device for applying compressive pressure against the leg, which device is easily applied and removed by the patient and is accordingly particularly suitable for home care.

Apart from this advantage, the construction and arrangement of elements of the therapeutic device of this invention provides further significant advantages which can best be described by reference to the physiology of the patient's leg.

As was previously stated, the important area to be subjected to compression is the muscular area on the sides and particularly on the back of the leg. The front of the leg is bony and hence does not require this treatment. Accordingly, the front side of the sleeve, which we can call the tongue portion thereof is not provided with sequential compression chambers. Moreover, the tongue portion is inelastic so that compression occurring at the back of the leg causes tension to be applied to the inelastic tongue portion which is in turn translated to pressure over the radius of curvature at the front of the leg.

It will also be seen from the foregoing description that there is no compression applied to the bottom of the foot. Since blood does not pool there, edema does not occur and consequently there is no need to apply compression. On the other hand, if the bottom of the foot portion were inflated to apply compression, the resulting pressure patterns would be changed if the patient stood on his feet, which the patient is indeed permitted to do when wearing the therapeutic device of this invention.

Yet another important advantage is obtained from the use of an outer sheet which is relatively stiff and inelastic and an inner film which is soft and compliant. Apart from the fact that it is desirable to have an abrasion resistant outer surface, this combination of outer sheet and inner film permits the inner film to conform substantially to the shape of the individual leg. Accordingly, zero pressure points are substantialy precluded, thus avoiding or lessening the so-called corrugation effect typically seen when prior hospital compressible sleeve devices are used on edematous legs.

Reference has been made above to the control of the supply of fluid pressure optionally being as described in our copending Application No. Serial No. (our case P15029EP).

This preferred aspect of the invention may be put into practice in various ways and one specific embodiment will be described by way of example to illustrate the invention with reference to the accompanying additional drawings in which:

Figure 6 is a plan view of a controller for a compressive pressure device of the present invention;

Figure 7 is a diagrammatic view of the device of the present invention; and

Figures 8 to 10 are diagrammatic views of electrical signals utilized in the device of the invention.

Referring now to Figure 7, there is shown a device generally designated 110 for applying compressive pressures to a patient's limb. The device 110 has a sleeve 112 for placement on the patient's limb having a plurality of inflatable chambers 114, 116, and 118 arranged longitudinally along the sleeve 112, including the lower ankle chamber 114. Preferably it is chamber 114 which is monitored.

The device 110 has a linear oscillator compressor 120 for forming a fluid, such as gas, under pressure. The compressor 120 is energized by an electrical cord 122 which may be connected to a suitable source of electrical energy by a plug 123, and which has a triac 124 electrically connected to the cord 122 for turning power on and off to the compressor 120.

The output of the compressor 120 is connected by a conduit 126 to a plurality of solenoid valves 128, 130, and 132 which control distribution of the pressurized fluid from the compressor 120 to the sleeve chambers 114, 116, and 118 by associated conduits 114a, 114b, and 114c in a manner forming a compressive pressure gradient which decreases from the lower chamber 114 to the upper chamber 118 of the sleeve 112. A conduit 134 is connected in fluid communication with the conduit 114a extending from the ankle chamber 114, and the conduit 134 is connected to a pressure transducer 136 which generates an electrical signal over an electrical lead 138 to a central processing system 141 (hereinafter "CPS") and to a suitable display 140 for indicating the pressure in the chamber 114.

The CPS 141 is preset for a desired predetermined pressure, as will be described below, and the CPS 141 is electrically connected by an electrical lead 142 to the triac 124. The CPS 141 compares the selected desired predetermined pressure with the pressure measured by the transducer 136. The CPS 141 forms a sine wave signal, as shown in Figure 8, and rectifies the signal of Figure 8 into a plurality of electrical pulses, such as positive pulses, as shown in Figure 9. The CPS 141 normally generates a nominal number of pulses, such as 148, during a specified period of time. In response to the difference between the selected and measured pressures, the CPS 141 selects any number of the pulses of Figure 9 by inhibiting or filtering a calculated number of pulses to form the modified pulse pattern, as shown in Figure 10. The formed pulses are connected to the triac 124 over the lead 142 in order to control the

fluid pressure formed by the compressor 120 by energizing and deenergizing the compressor 120 responsive to the formed number of pulses, the number of which may vary during different time periods, to obtain the desired predetermined pressure. Thus, the output of the compressor 120 is controlled by means of pulses through feedback pressure control for the compressor 120.

A controller 144 with a suitable display is illustrated in Figure 6 which is utilized to control the device 110. The controller 144 has a cycle monitor portion 146, and a fault indicator display 148. The controller 144 has a pressure display 140, previously described in connection with Figure 7, which is used to show the set pressure, preferably the ankle pressure. An additional display 160 to the right of the cycle monitor 146 indicates whether or not the controller 144 has achieved the set pressure. The control membrane switches 152 and 154 are used for increasing and decreasing the set ankle pressure. To the left of the fault indicator 148 is hidden a membrane switch 156, which, when pressed, will cause the pressure display 140 to monitor ankle pressure for one complete cycle, e.g. of 72 seconds, after which the display 140 will revert to displaying the set pressure. During this monitoring phase, there should be no difference between the set pressure and the final compression pressure displayed.

When the controller 144 is first turned on the following sequence of events will occur. The controller 144 will default to a set pressure of 45 mmHg and will show this on the display 140. The compressor 120 will come to full output during the inflation portion of the cycle in order to more quickly fill the sleeve 112. During this start up phase, the high pressure alarm 162 can be ignored, if necessary; however, as soon as the pressure at the end of the ankle compression exceeds some predetermined minimum value, the output of the compressor 120 will be reduced. The light emitting diode (hereinafter "LED") 160 indicating that the set pressure has not been achieved is lit. Within four cycles, the system reaches its set pressure. At that time, the running LED 164 will light, and the previous LED 160 will extinguish. If a pressure other than 45 mmHg is desired, pressing the upper pressure adjusting membrane switch 152 will increase the set pressure in 1 mmHg increments for each pressing of the switch. Holding the switch down for two seconds will result in the set pressure increasing at a rate of approximately 1 mmHg each half second for as long as the switch is held. Pressing the lower membrane switch 154 will decrease the set pressure in the same way. The set pressure range is 25 mmHg to 65 mmHg. When the set pressure is changed, the running LED 164 is extinguished and the adjusting LED is lit. The adjustment is completed within four cycles.

Reference has been made above to the coupling adapter 51 optionally being as described in our copending Application No. Serial No. (our case P15025EP).

This preferred aspect of the invention may be put into practice in various ways and one specific embodiment will be described by way of example to illustrate the invention with reference to the accompanying additional drawings in which:

Figure 11 is a sectional view of a connection device of the present invention;

Figure 12 is a fragmentary plan view of an intermediate member, taken partly in section, and taken substantially as indicated along the line 12-12 of Figure 11; and

Figure 13 is a fragmentary plan view of a connector, taken partly in section, and taken substantially as indicated along the line 13-13 of Figure 1.

Referring now to Figures 11 to 13, there is shown a connection device generally designated 210 having an intermediate member 212, a first connector 214, and a second connector 216. The intermediate member 212 has a pair of opposed first and second sides 221 and 223, and a plurality of spaced annular walls 218a, 218b, 218c, 218d, and 218e defining a plurality of separate annular channels 220a, 220b, 220c, and 220d extending substantially peripherally around the intermediate member 212. The intermediate member 212 has first and second generally circular elastic walls 222 and 224 covering the opposed first and second sides 221 and 223 of the intermediate member 212 and enclosing the channels 220a, 220b, 220c, and 220d. As shown, the walls 222 and 224 have a plurality of openings 226 and 227 respectively extending therethrough separately communicating with each of the channels 220a, 220b, 220c, and 220d of the intermediate member 212. Also, the intermediate member 212 has a pair of opposed bosses 228 which are received in apertures 230 of the first and second walls 222 and 224 in order to retain the first and second walls 222 and 224 in place on the intermediate member 212. In this configuration at least one of the openings 226 in both the walls 222 and 224 communicate with each of the channels 220a, 220b, 220c, and 220d in the intermediate member 212.

The intermediate member 212 has a plurality of conduits 232a, 232b, 232c and 232d including associated passageways in the intermediate member 212 which communicate with a source of fluid which passes through the conduits 232a, b, c, and d and separate ports 234a, 234b, 234c, and 234d into the channels 220a, 220b, 220c, and 220d.

The first connector 214 is adjacent the first wall 222, and the second connector 216 is adjacent the

second wall 224. Since the first and second connectors 214 and 216 are substantially identical in structure, like reference numerals will be used to designate like parts in the connectors 214 and 216. The first and second connectors 214 and 216 have a plurality of separate annular walls 238a, 238b, 238c, 238d and 238e defining separate annular channels 236a, 236b, 236c, and 236d extending substantially peripherally around the connector 214 and 216. Each of the channels 236a, b, c, and d of the first connector 214 separately communicate with the openings 226 in the first elastic wall 222 associated with the channels 220a, 220b, 220c, and 220d of the intermediate member 212. Similarly, each of the channels 236a, b, c and d of the second connector 216 separately communicate with the openings 227 of the second elastic wall 224 such that the channels 236a, b, c, and d of the second connector 216 communicate with the channels 22a, b, c, and d of the intermediate member 212.

The first and second connectors 214 and 216 each have a set of conduits (first conduits 240a, b, c, and d and second conduits 241a, b, c and d) which communicate respectively through respective ports (242a, b, c, and d and 243a, b, c and d) with the separate respective channels 236a, b, c, and d and 237a, b, c and d.

Thus, in use, the fluid under pressure passes through the conduits 232a, b, c, and d into the channels 220a, b, c, and d of the intermediate member 212, through the openings 226 of the walls 222 and 224 into the channels 236a, b, c, and d of the first and second connectors 214 and 216 and through the conduits 240a, b, c, and d into separate chambers of a pair of sleeves, with each sleeve being associated with one of the connectors 214 and 216.

The first and second connectors 214 and 216 have a bore 244 and 245, respectively, extending therethrough, the first and second walls 222 and 224 have bores 246 and 248, extending therethrough, and the wall 218a of the intermediate member 212 has a bore 250 extending therethrough. The connection device 210 has an elongated bolt 252 having a knob 254 at one end, and a threaded portion 256 adjacent the other end. The bore 245 of the second connector 216 is threaded 257 to receive the threaded portion 256 of the bolt 252. Thus the bolt 252 may be utilized to releasably assemble the first and second connectors 214 and 216 to the intermediate member 212 while permitting rotation of the first and second connectors 214 and 216 relative to the intermediate member 212. However, in all rotational positions of the first and second connectors 214 and 216, the channels 220a, b, c, and d of the intermediate member communicate through the openings 226 of the first and second walls 222 and 224 with the respective channels 236a, b, c, and d of the first and second connectors 214 and 216.

The first and second connectors 214 and 216 have an outer annular wall 270 having a plurality of spaced inwardly directed teeth 258 which are releasably received in associated notches 260 of the intermediate member 212 in order to releasably retain the first and second connectors 214 and 216 at a plurality of desired rotational positions relative to the intermediate member 212. Thus, the first and second connectors 214 and 216 may be moved to a number of desired rotatable positions, such as eight, and may be releasably secured in place by tightening the bolt 252. At the same time, the first and second elastic walls 222 and 224 provide seals between the intermediate member 212 and first and second connectors 214 and 216 to prevent leakage in the connection device 210. The first and second connectors 214 and 216 have an outer generally circular recess 262 to receive associated generally circular plates 264, with the plates 264 being retained in place in a suitable manner, such as by adhesive. The plate 264 of the first connector 214 has an aperture 266 to permit passage of the bolt 252 therethrough.

In use, the bolt 252 may be removed from the connection device 210 in order to readily disassemble the first and second connectors 214 and 216 and associated sleeves from the intermediate member 212, and permit easy assemblage of the first and second connectors 214 and 216 and the associated sleeves to the intermediate member 212 by securement of the bolt 252 in the connector device 210.

Reference has been made above to optional sequential pressurization and depressurization as described in our copending Application No. Serial No. (our case P15026EP).

This preferred aspect of the invention may be put into practice in various ways and a number of specific embodiments will be described to illustrate the invention with reference to the accompanying additional drawings, in which:

Figure 14 is a perspective view of a controller for a compressive pressure device of a first embodiment of this aspect of the present invention;

Figure 15 is a plan view of an internal portion of the controller of Figure 14;

Figure 16 is a perspective view of a sleeve for use with the device of Figure 14;

Figure 17 is a diagrammatic view of the controller of Figure 14;

Figure 18 is a fragmentary elevational view of a second embodiment of a device in accordance with this aspect of the present invention;

Figure 19 is a graph illustrating pressure profiles as plotted versus time formed by a device

in accordance with this aspect of the present invention;

Figure 20 is a plan view of an exhaust system for a third embodiment of a device in accordance with this aspect of the present invention;

Figure 21 is an exploded view of a relief valve for use in the device of Figure 15 (the first embodiment);

Figure 22 is a sectional view of the device shown in Figure 21; and

Figure 23 is a sectional view of a sleeve for use in a fourth embodiment of this aspect of the present invention.

Referring now to Figure 14, there is shown a controller 320 for a compressive pressure device generally designated 318 of the invention, with the controller 320 having a display panel 322. The display panel 322 has a first 'lo' switch 324 and a second 'hi' switch 326 for controlling two different levels of compression for a sleeve during use of the device.

Referring now to Figures 15 to 17, the controller 320 has a plurality of closed walls 328 defining an accumulator or cavity 330 with a fixed volume for compression of fluid. The controller or device 320 has a compressor 332 which discharges gas into the accumulator 330, and builds up pressure in the accumulator 330 over a period of time, such as for ten seconds to a pressure of 80 to 100 mmHg. The controller 320 of the device 318 has a plurality of solenoid valves 334a, 334b, 334c, and 334d in the accumulator 330 associated with ports 336a, 336b, 336c, and 336d of respective conduits 338a, 338b, 338c, and 338d, with the valves 334a, 334b, 334c, and 334d being utilized to open and close the ports 336a, 336b, 336c, and 336d of the conduits 338a, 338b, 338c, and 338d as desired. The device 318 has a compression sleeve 340 having a plurality of inflatable chambers 342 disposed longitudinally along the sleeve 340, including a separate chamber 344 for placement against the foot, and a separate chamber 346 for placement against the knee. The sleeve 340 has a connector 348 for connection of conduits 349 communicating with the chambers 342 of the sleeve 340 with the conduits 338a, 338b, 338c, and 338d. The conduit 338a is connected to an ankle chamber 343a of the sleeve 340. The conduit 338b is connected to the foot and knee chambers 344 and 346 of the sleeve 340. The conduit 338c is connected to a calf chamber 343b of the sleeve 340. The conduit 338d is connected to a thigh chamber 343c of the sleeve 340.

The operation of the device is as follows. The valves 334a, 334b, 334c, and 334d are closed in order to prevent passage of fluid through the ports 336a, 336b, 336c, and 336d while the compressor 332 charges the accumulator 330 with the pressurized gas. Next, the valve 334a is opened to permit passage of pressurized fluid from the accumulator 330 through the port 336a and conduit 338a into the ankle chamber. 343a in order to inflate the ankle chamber and apply a compressive pressure by the ankle chamber against the patient's limb, with the pressure curve or profile 350 of the ankle chamber being illustrated in Figure 19 there pressure in mmHg is plotted against time in seconds. As shown, the ankle chamber is inflated while the pressure curve or profile 352 of the accumulator 330 decreases as a function of time to a value approximately the maximum ankle pressure. After a sufficient time of inflation and increase of pressure in the ankle chamber, the valve 334c is opened to permit passage of the pressurized fluid through the port 336c and conduit 338c to a calf chamber 343b in the sleeve 340, resulting in inflation of the calf chamber with the pressure curve or profile 354 of the calf chamber being illustrated in Figure 19. After sufficient inflation of the calf chamber, the valve 334d is opened to permit passage of pressurized fluid through the port 336d and conduit 338d to a thigh chamber 343c of the sleeve 340, and the thigh chamber is inflated in order to increase pressure in the thigh chamber, as illustrated by the curve 357 in Figure 19. In this manner, the ankle, calf and thigh chambers are sequentially inflated at spaced intervals of time during intermittent compression cycles. As can be seen in Figure 19, the pressure 352 of the accumulator 330 is substantially identical to the pressure in the ankle and calf chambers.

After inflation of the thigh chamber, at a specified time determining a set pressure 356, the valve 334b is opened in order to open the port 336b and establish communication by the accumulator 330 with the conduit 338b. In turn, the conduit 338b establishes fluid communication with the foot chamber 344 and knee chamber 346 through a downstream portion 338b′ of the conduit 338b. Also, the conduit 338b establishes communication with a relief valve 358 through a conduit portion 338b″ which communicates with the conduit 338b. At this time, the valves 334a, 334c, and 334d are opened to permit passage of the fluid from the ankle, calf and thigh chambers into the accumulator 330, and passage through the port 336b associated with valve 334b into the conduit 338b. At this time, a majority of the pressurized fluid passes to the relief valve 358 which serves as an exhaust for the device 318, as will be further described below, while the remainder of the fluid passes through the downstream conduit portion 338b′ to a lesser extent due to the substantial length of the downstream conduit portion 338b′. As will be further described below, the relief valve 358 allows a drop of pressure in the accumulator 330 to a substantially lower predetermined pressure, such as 10

mmHg, in addition to establishing such a pressure in the foot chamber 344 and knee chamber 346. At this time, the valves 334a, 334b, 334c, and 334d are closed, and the compressor 332 continues to remain in operation, such that the pressure in the accumulator 330 again begins to substantially rise due to the compressor 332.

As shown in Figures 21 and 22, the relief valve 358 has a first body portion 360 having a hollow stem 362 at one end for connection to the conduit portion 338b". The first body portion 360 has an outer annular flange or wall 364 with outer threads 366. The relief valve 358 has a second body portion 368 having an inner annular flange or wall 370 having inner threads 372 which cooperate with the threads 366 of the flange 364 in order to releasably secure the second body portion 368 at an adjustable position on the first body portion 360. An outer end of the second body portion 368 has an inwardly directed cylindrical portion 374 having a recess 376 for purposes which will be described below, and a plurality of elongated slots or opening means 392 extending therethrough. The relief valve 358 has a valve member or plunger 378 having an elongated stem 380 which is received in the recess or cavity 376 of the cylindrical portion 374. The valve member 378 has an annular collar 382 on the stem 380, and a helical spring 384 which extends between the cylindrical portion 374 and the collar 382. The valve member 378 has an inner outwardly diverging annular valve portion 386, which faces an elastic O-ring 388 located at an inner portion of a cavity 390 defined by the flange 364. The spring 384 biases the valve member 378 toward the first body portion 360 of the relief valve 358, and biases the valve portion 386 toward the O-ring 388 which serves as a seat. The amount of force exerted by the valve portion 386 against the O-ring 88 may be adjusted through suitable adjustment of the first body portion 360 relative to the second body portion 368 through use of the cooperating threads 366 and 372.

In use, the fluid under pressure passes through the stem 362, between the O-ring 388 and the valve portion 386, and through the slots 392 in order to permit exhaust of the fluid under pressure from the accumulator 330.

In use, the pressurized fluid passing through the relief valve 358 moves the valve portion 386 away from the O-ring 388 such that equilibrium is reached between the plunger spring 384 and pressure in order to permit passage of fluid from the exhaust through the slot 392, after which the valve member 378 closes against the O-ring 388. The pressurized fluid will continue to bleed through the relief valve until the valve 334b closes to cause fluid pressure to again build in the accumulator 330.

In this manner, the chambers 342 of the sleeve 340 are sequentially inflated to form a pressure gradient, and during exhaust of the chambers 342 in the sleeve 340 through the relief valve 358 at least once, a residual or base static pressure, such as 10 mmHg, remains in the ankle, calf, and thigh chambers, as well as being introduced into the foot and knee chambers 334 and 336. The residual or base static pressure remains during non-inflation of the ankle, calf, and thigh chambers during periodic decompression cycles, and the residual pressure curve or profile 394 is illustrated as a function of time in the graph of Figure 19 for the foot chamber 344 and knee chamber 346, and remains substantially the same throughout operation of the device 318. Thus, the residual pressure remains in the ankle, calf, and thigh chambers, and this pressure makes the sleeve 340 less sensitive to fit on a patient's limb so that the sleeve 340 could be loosened to a greater extent. Also, the demands imposed on the compressor 332 to inflate the sleeves 340 are substantially lessened, such that a much smaller and less powerful compressor 332 may be utilized in the device 318 which substantially reduces its cost. The described embodiment in connection with Figures 14 to 17 may be utilized by the patient at home, and is primarily for the treatment of venous ulcers and edema. Such a system is intended to be used intermittently on patients who are awake and alert. In summary, the device 318 passes through a few compression cycles to inflate the chambers 342 before the base line or residual pressure is stablished in the chambers 342. Thus, once the residual pressure is established in the ankle, calf, and thigh chambers, the requirements for fluid under pressure in order to increase the pressure of the chambers 342 to the desired pressure profiles is substantially decreased, thus decreasing the demands upon the nature of the compressor 332.

Another embodiment of the present invention is illustrated in Figure 18. In this embodiment, the conduit 338b extends to a lower portion of a container 396 containing a supply of liquid L, such as water. The gas under pressure passes through the conduit 338b, and bubbles through the liquid L in order to establish the residual pressure in the sleeve chambers during the non-inflation or decompression periods of the device. In this manner, the residual pressure of the sleeve 340 is controlled through use of the passage of gas through the liquid L. The container 396 may be attached to a side of the controller 320 for convenience, if desired.

Another embodiment of a device 398 for the exhaust of chambers from a sleeve is illustrated in Figure 20, in which like reference numerals designate like parts. In this embodiment, the device

398 has a plurality of solenoid valves 400a, 400b, 400c, and 400d. The valve 400a is connected by a conduit 402 to the valve 400c, and the valve 400c is connected by a conduit 404 to the valve 400d. In turn, the valve 400d is connected by a conduit 406 to a pressure relief valve 358 of the type previously described in connection with Figures 21 and 22 which operates in the same manner. In this embodiment, the valves 400a, 400c, and 400d, which are respectively connected to the ankle, calf, and thigh chambers of the sleeve, are simultaneously opened in order to permit passage of the fluid from the ankle, calf, and thigh chambers through the conduits 402, 404, and 406 to the relief valve 358 which serves as an exhaust for the fluid under pressure. The valve 358 closes at a predetermined pressure, e.g. 5-10 mmHg, as previously described, in order to establish the base line or residual pressure in the chambers such that the requirements for subsequent inflation of the chambers and demands for the compressor are minimized. The device 398 of Figure 20 is designed primarily for use in the hospital for the treatment of deep venous thrombosis, and the sleeve for this device may not have a foot or knee chamber. The valve 400b is used in connection with a ventilation chamber in the sleeve which passes air onto the patient's limb such that the gas is continuously expelled to the atmosphere, and need not be connected to the relief valve 358.

Another embodiment of the present invention is illustrated in Figure 23, in which like reference numerals designate like parts. In this embodiment, there is shown a sleeve 408 having a plurality of inflatable chambers 410 disposed longitudinally along the sleeve 408. The device of Figure 23 has an outer fluid impervious wall 412 which closes the chambers 410 of the sleeve 408 in sealing engagement to form a chamber 416 between the wall 412 and chambers 410. The device has a plurality of conduits 414 which are connected to the chambers 410 of the sleeve 408 and to the chamber 416 between the wall 412 and the chambers 410. The chambers 410 of the sleeve 408 are inflated in a suitable manner through the conduits 414, as previously described, while the chamber 416 closed by the wall 412 is also inflated over the chambers 410 in order to establish a residual or base line pressure outside of the chambers 410 for purposes as previously described.

In a preferred form, the device of Figure 23 has an adapter 418 which is connected between a conduit 420, such as the conduit 338b connected to the solenoid valve 334b of Figure 17, with the adapter 418 containing a pressure regulator which may be modified by a suitable adjustment device 422 such that a desired pressure may be maintained accurately in the chamber 416. In an alternative form, the conduit 338b from the controller 320 may be connected directly to the chamber 416 of the device of Figure 23 in order to establish the residual pressure.

Claims

1. A sleeve for applying compressive pressures against a patient's limb from a source of pressurized fluid, characterized in that it comprises an elongated sheath (10) preferably multi layered defining a plurality of compressive chambers (12) which may be generally limb encircling, the said sheath having an open proximal end (60) and a closed distal end, the said sheath being adapted to receive a patient's limb through its open proximal end; the said sheath having a front portion (19) for juxtaposition with the front surface of a patient's limb, and a back portion (17) for juxtaposition with the back surface of a patient's limb; the said front and back portions of the said sheath carrying mutual engagement means (62,64) and being adapted to be wrapped over each other to permit engagement of the mutual engaging means, permitting girthwise adjustment of the said sleeve about a patient's limb.

2. A sleeve for applying compressive pressures about a patient's limb as claimed in Claim 1 characterized in that the said front portion and the said rear portion have a common coinciding edge (54) only partway along the length of the side of the said sheath from the said proximal end to the said distal end, to permit openability of the said sheath, thus facilitating entry of a patient's limb into the sheath.

3. A sleeve for applying compressive pressures about a patient's limb as claimed in Claim 1 or Claim 2 characterized in that the said back portion inciudes a cushion pad (36) for the juxtaposition of a patient's foot thereagainst.

4. A sleeve for applying compressive pressures about a patient's limb as claimed in any one of Claims 1 to 3 characterized in that a compressive chamber (34) is longitudinally disposed in the said front portion of the said sheath, extending from the distal end thereof, to or towards the proximal end thereof.

5. A sleeve for applying compressive pressures about a patient's limb as claimed in any one of Claims 1 to 4 characterized in that it includes a plurality of compressive chambers (38,40,42,44) extending transversely across the said back portion (17) of the said sheath so as to extend around the fleshy portions of a leg when the sheath is wrapped therearound.

6. A sleeve as claimed in any one of Claims 1 to 5 characterized in that the sheath comprises an

outer sheet (14) which is relatively stiff and inelastic so that it remains relatively flat upon inflation on introduction of pressure fluid within the said compressive chambers; and an inner sheet (22) which is soft and compliant, so that upon inflation the said inner sheet conforms substantially to the shape of the said limb.

7. A sleeve as claimed in any one of Claims 1 to 6 characterized in that the said front portion is adapted for placement against the bony front of a patient's leg, the said front portion being substantially inelastic, whereby when compression occurs by introducing the said fluid within the said chambers, tension is applied across the curvature of the said front portion, which tension translates into a pressure over the radius of curvature along the front of the said leg.

8. A sleeve as claimed in Claim 7 characterized in that the said inelastic front portion and the said back portion of the said sheath when secured to enclose a patient's leg provide pressure chamber means (34) for filling the hollow portions at either side of the said bony portion of the leg, whereby tension on the said inelastic front portion will result in compression at that portion of the leg.

9. A sleeve as claimed in Claim 8 characterized in that the said pressure chamber means (34) in the said front portion is partially bifurcated.

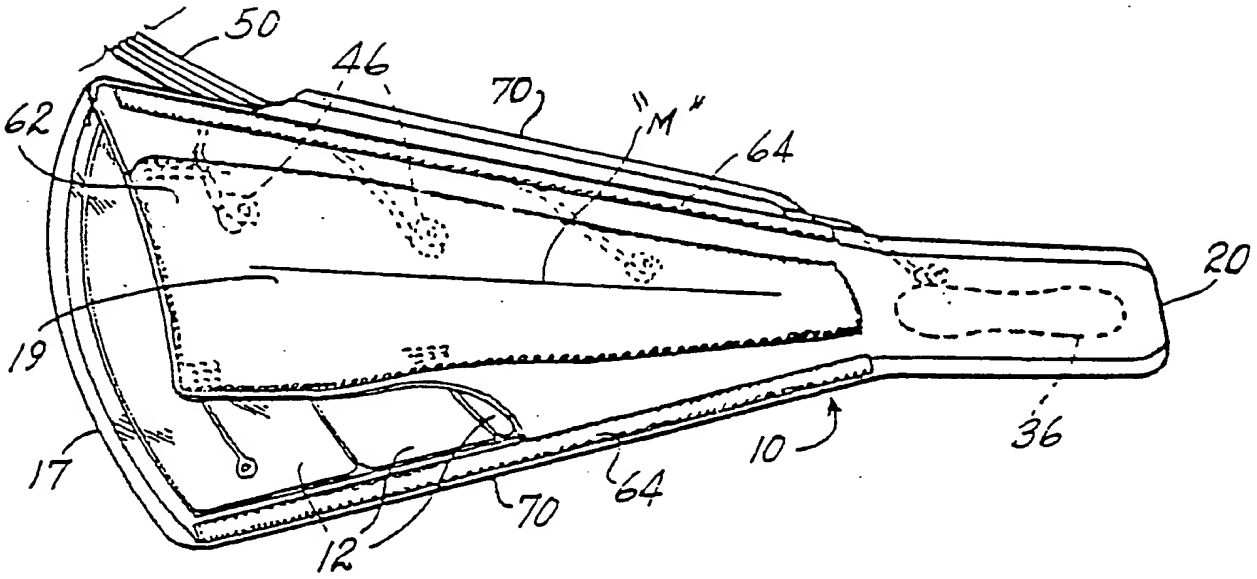
10. A sleeve as claimed in any one of Claims 1 to 9 characterized in that it includes a portion adapted to enclose a patient's foot when the said front and back portions are wrapped over and secured together, the said foot portion in juxtaposition with the bottom of the said patient's foot containing no compressive chamber and thereby being non-inflatable.

11. A method of applying sequentially variable compressive pressures, in addition to a constant base pressure, against a patient's limb, from a source of pressurized fluid, comprising providing a multi-layered elongated sheath around the limb, the sheath defining a plurality of generally limb encircling compressive chambers having an open proximal end and a closed distal end, the said sheath receiving the patient's limb through its open proximal end; the said sheath also having a chambered front portion for juxtaposition with the front surface of a patient's limb, and having a chambered back portion for juxtaposition with the back surface of a patient's limb; the said sheath also having a generally oval shaped pad arranged near the distal end thereof, with a compressible chamber disposed about the periphery of the said pad; the said front portion chamber and said peripherally disposed compressible chamber being maintained at a constant base pressure therein while the said generally limb encircling compressive chambers are pressurized sequentially.

12. A method as claimed in Claim 11 characterized in that a sleeve as claimed in any one of Claims 1 to 10 is placed around the patient's limb.

13. In an elongated compressible sleeve device adapted for enclosing a length of an individual's limb and for applying compressive pressure thereo, the said device including inner and outer sheet materials, sealed together to define a plurality of pressurizable chambers, the said device further including inlet means for introducing a fluid to inflate the said chambers, whereby to apply the said compressive pressure against the said enclosed limb; the improvement wherein the said outer sheet is relatively stiff and inelastic whereby it remains relatively flat upon inflation by introducing the said fluid within said chambers, and the said inner sheet is soft and compliant whereby upon inflation the said inner sheet conforms substantially to the shape of the said enclosed limb.

FIG. 1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19
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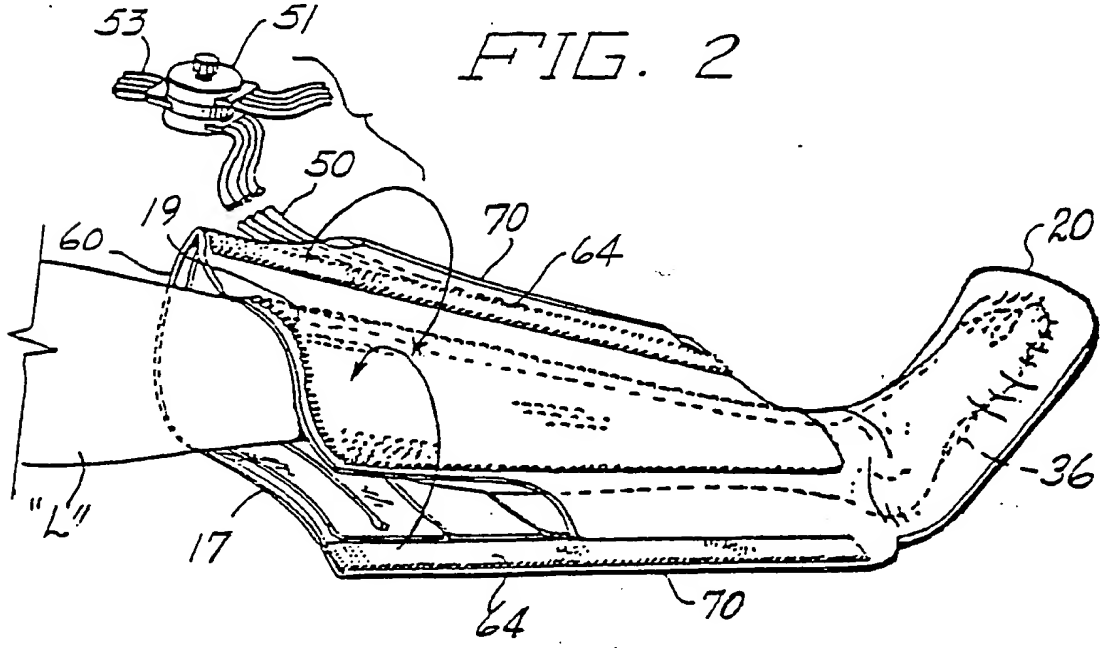
10
17
64
70
12

FIG. 2


53
51
50
19
70
20
60
64
36
"L"
17
64
70

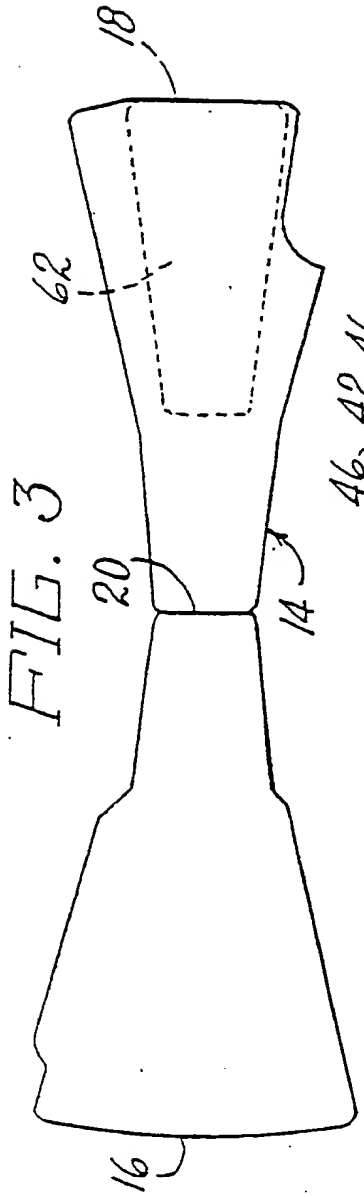


FIG. 3

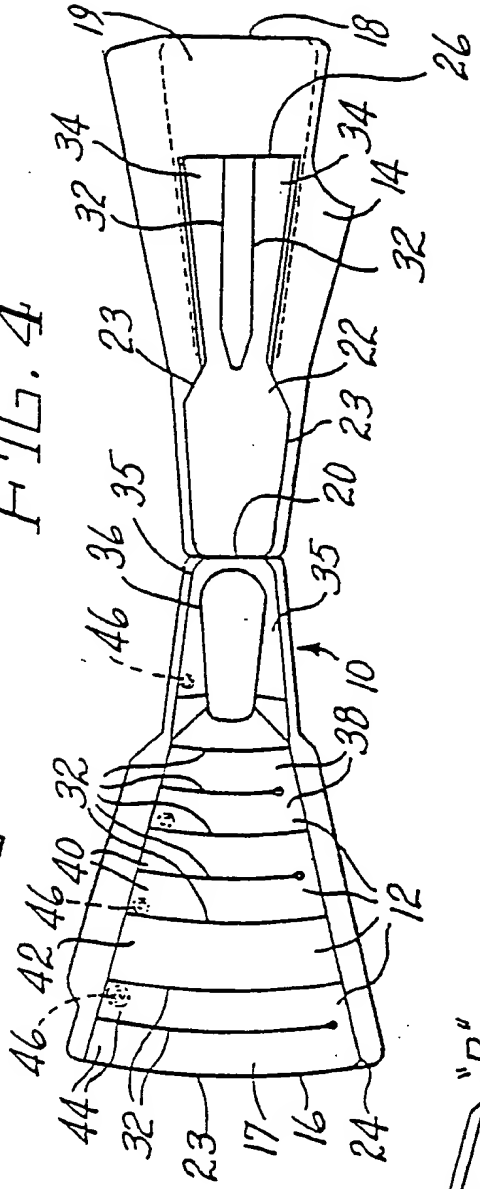


FIG. 4

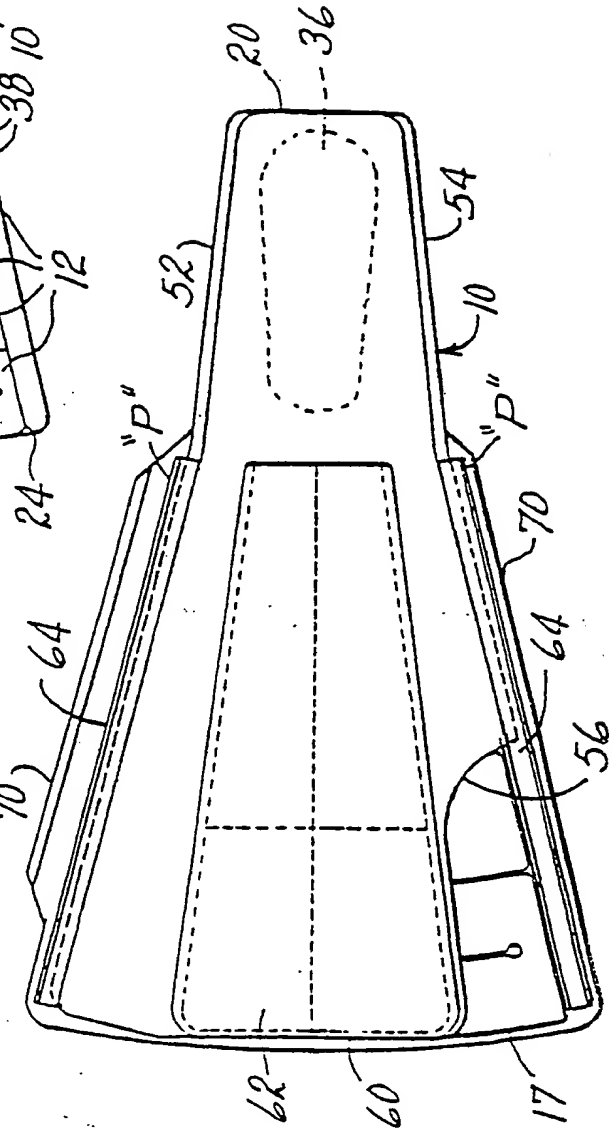


FIG. 5

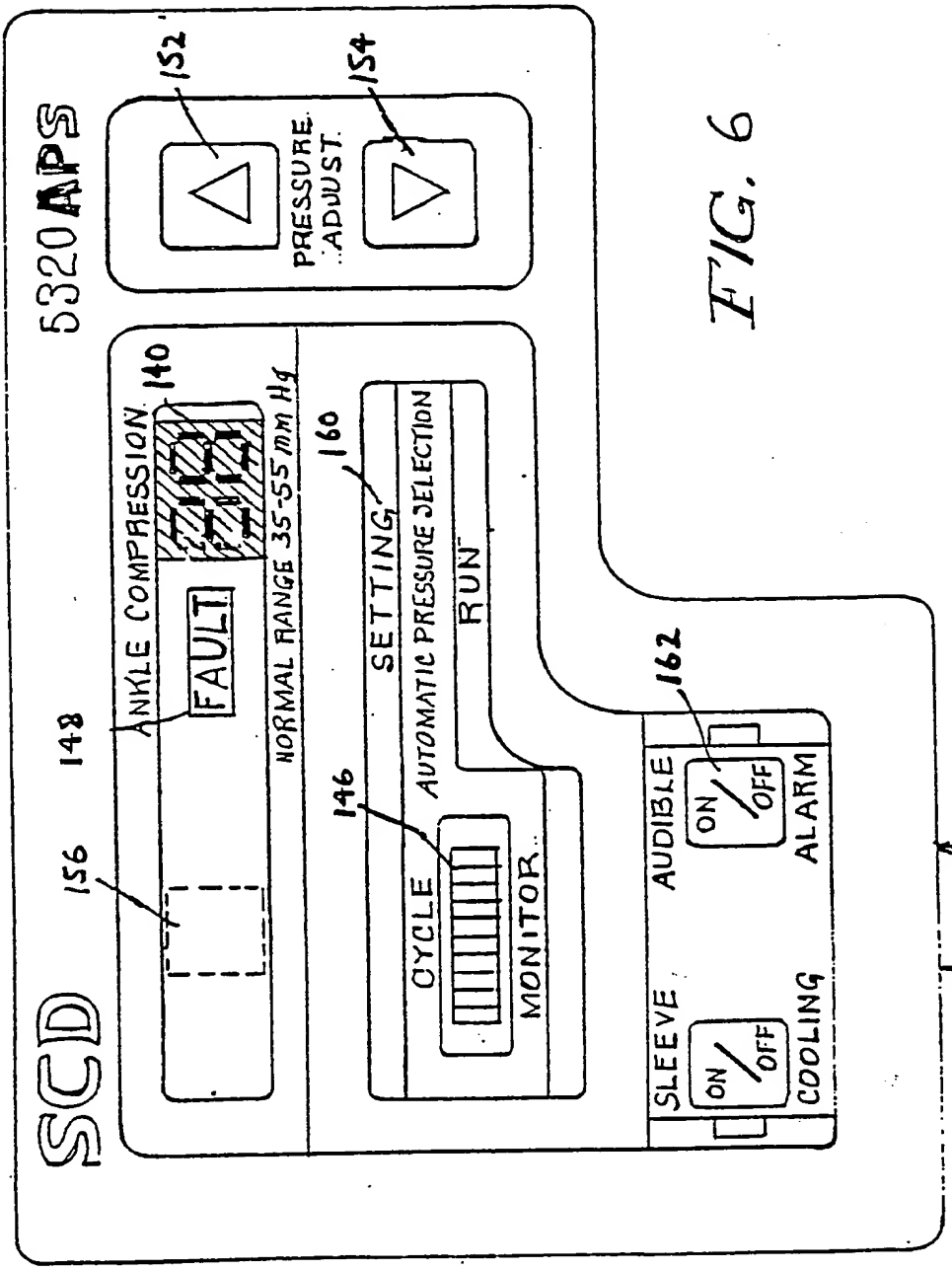

SCD
5320APS
148
156
ANKLE COMPRESSION
140
FAULT
NORMAL RANGE 35-55 mm Hg
160
SETTING
AUTOMATIC PRESSURE SELECTION
RUN
146
CYCLE
MONITOR
152
154
PRESSURE ADJUST
162
AUDIBLE ALARM
ON
OFF
SLEEVE COOLING
ON
OFF
144
110

FIG. 6

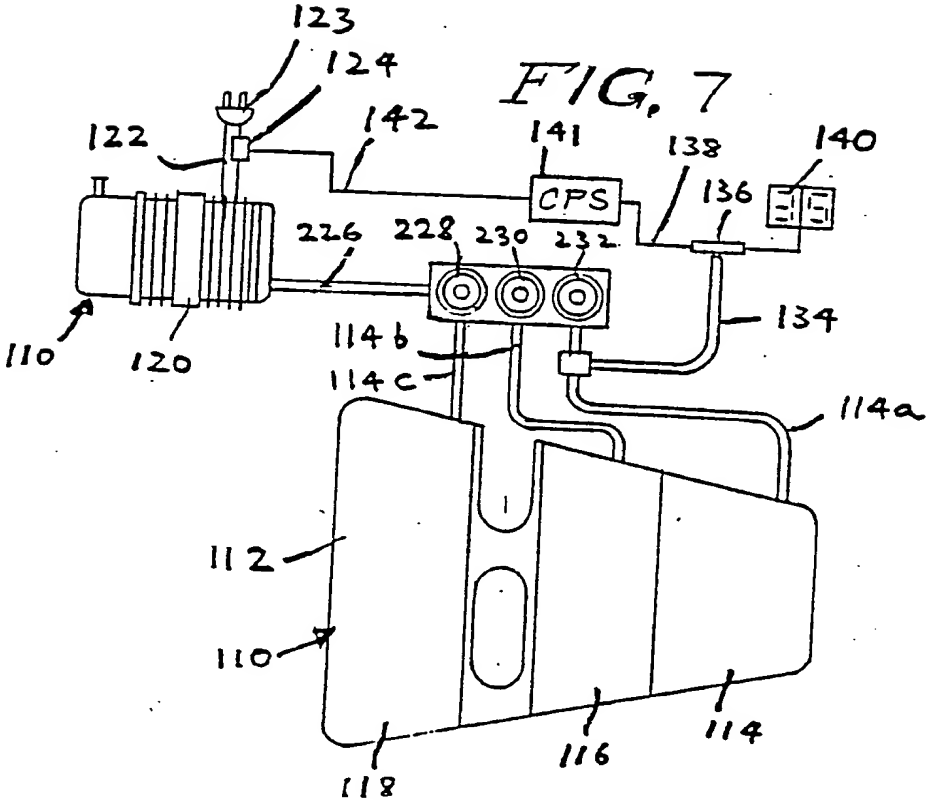


FIG. 7

FIG. 8

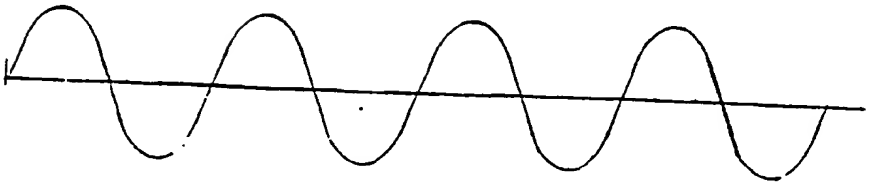


FIG. 9

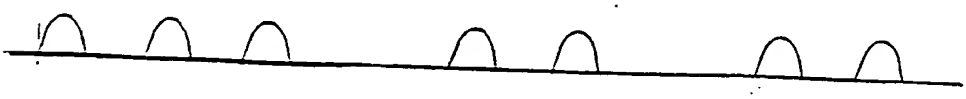
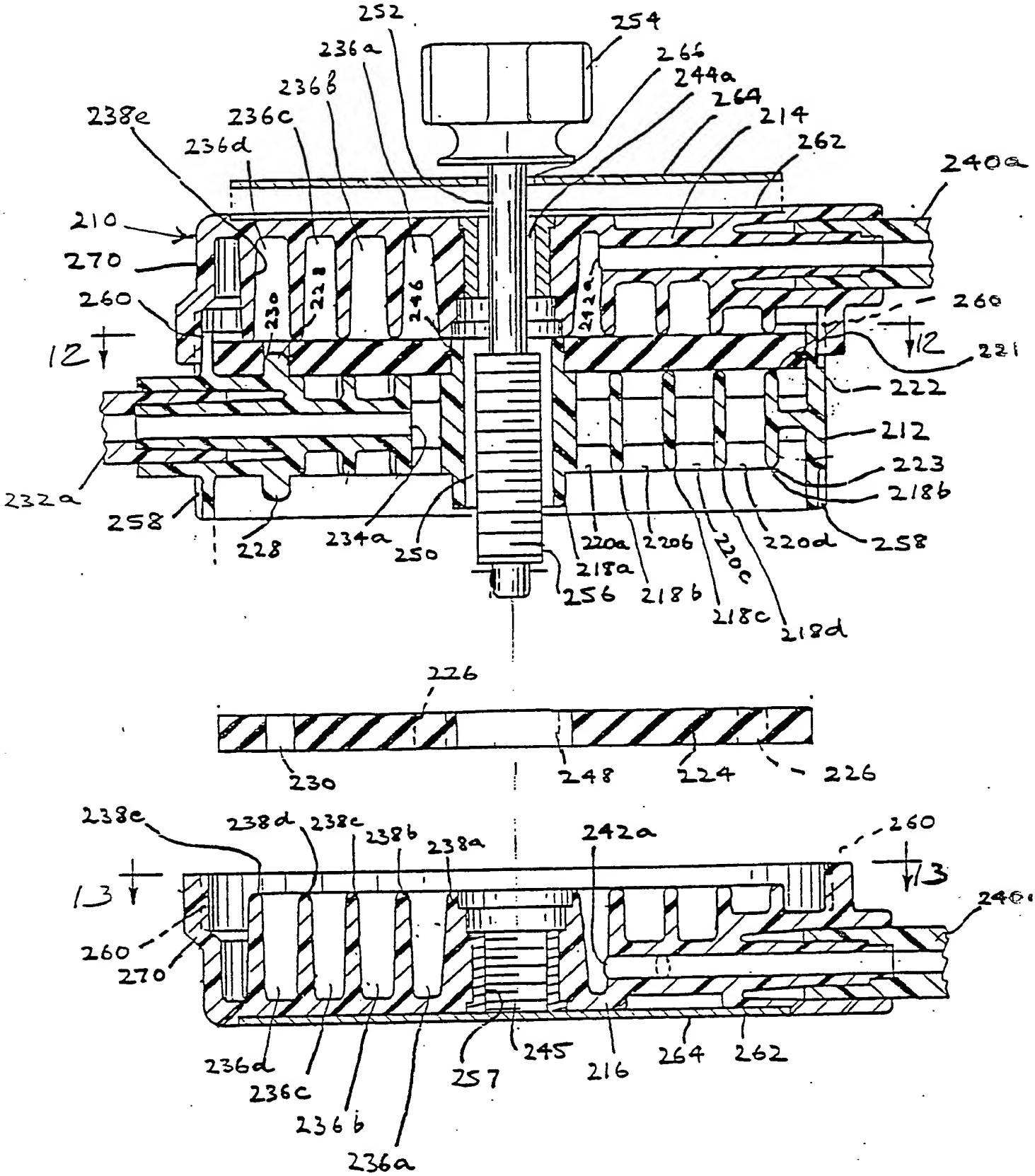


FIG. 10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244a
236b
264
214
238e
236c
262
236d
240a
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260
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246
242a
260
12
12
221
222
212
223
218b
232a
258
228
234a
250
220a
220b
220c
220d
258
218a
256
218b
218c
218d
226
230
248
224
226
238e
238d
238c
238b
238a
242a
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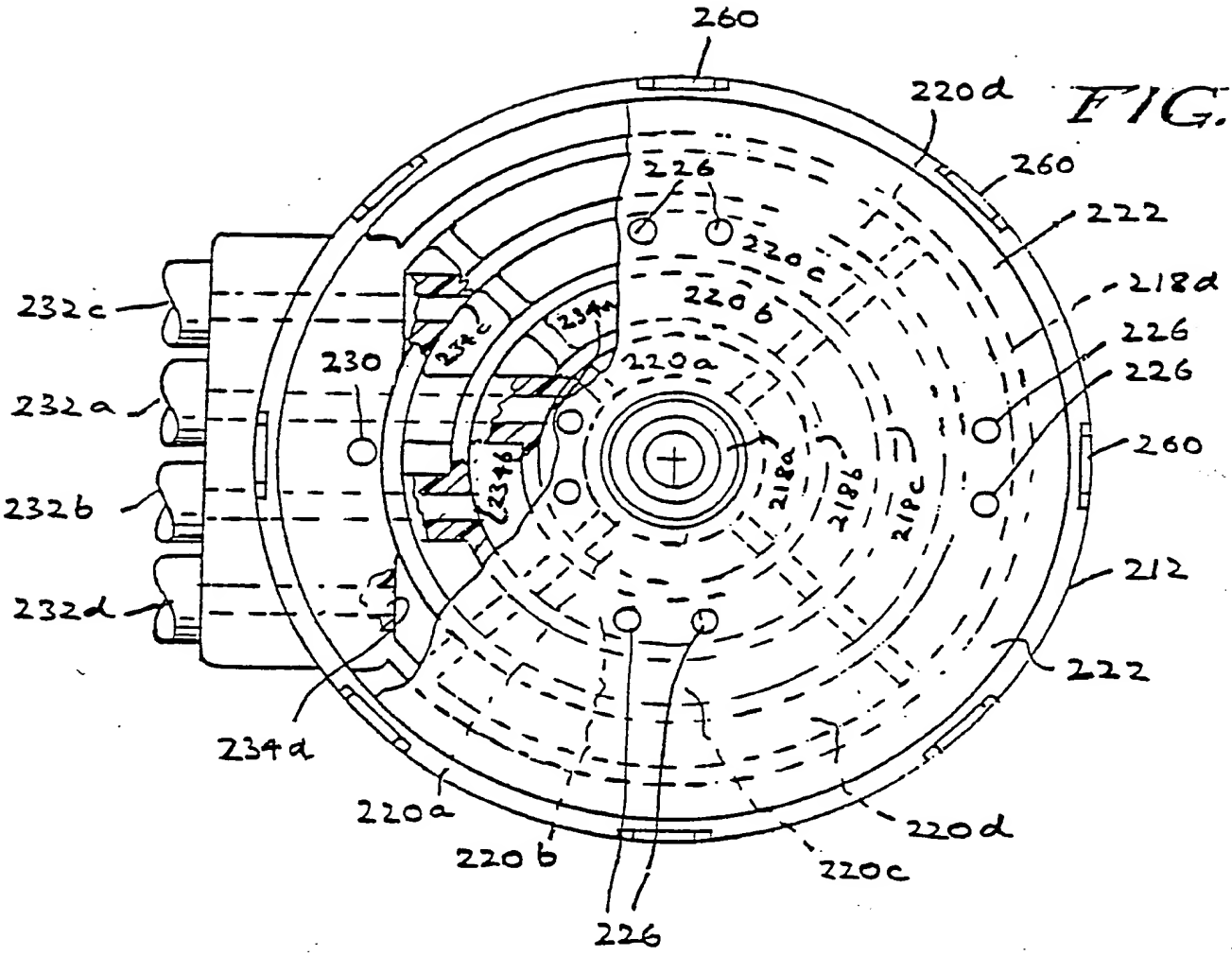
13
240a
260
270
236d
236c
236b
236a
257
245
216
264
262

FIG. 11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222
220c
220b
218d
232c
234c
234a
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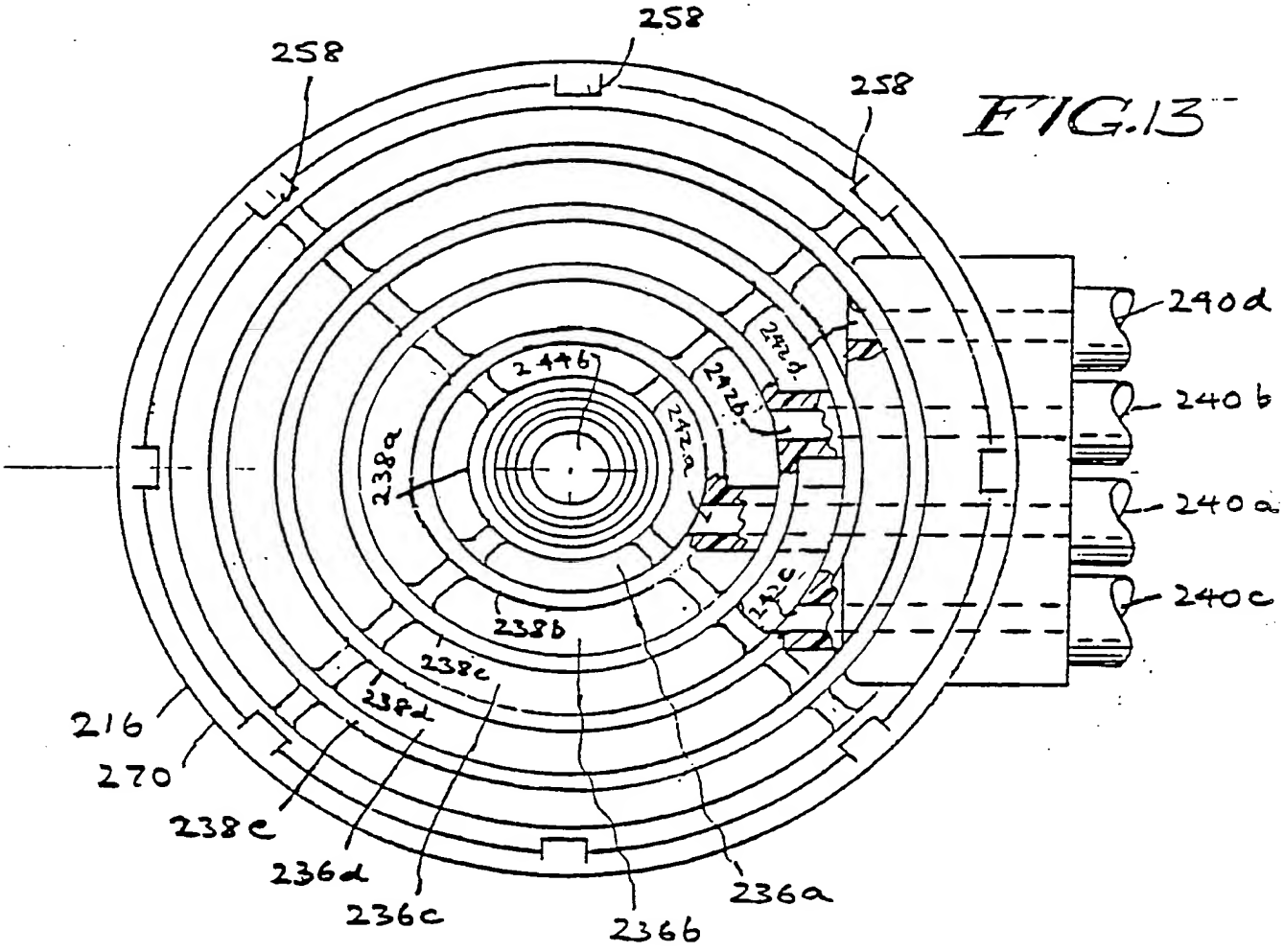
232a
234b
218a
218b
218c
260
232b
212
232d
222
234d
220a
220d
220b
220c
226

FIG. 12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242d
242b
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216
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238e
236d
236c
236b
236a

FIG.13

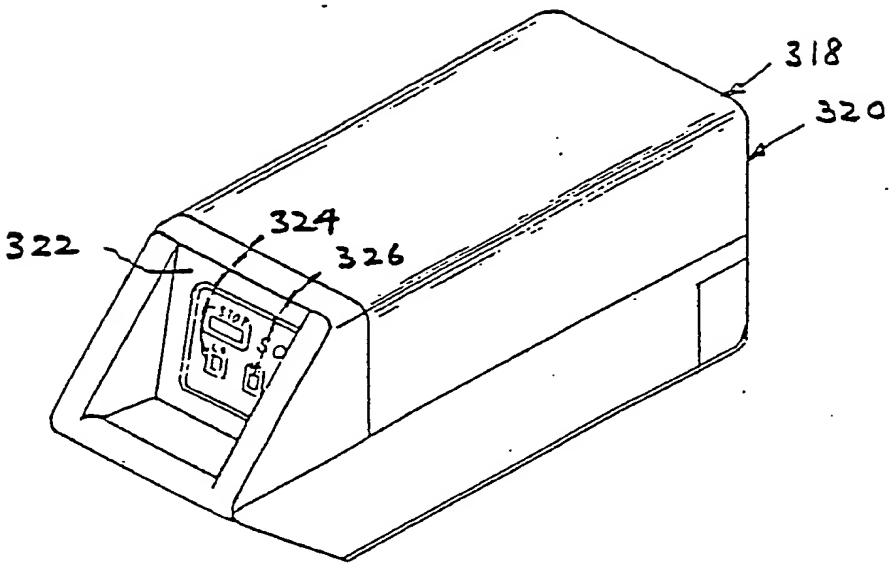


FIG. 14

FIG. 15

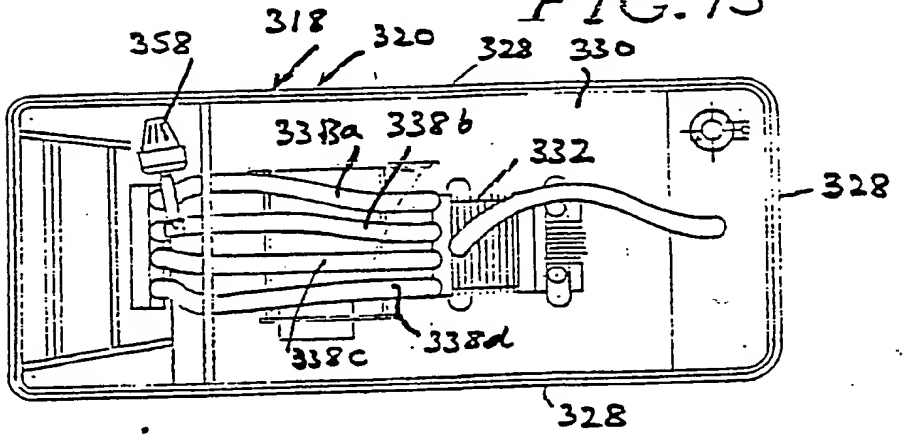
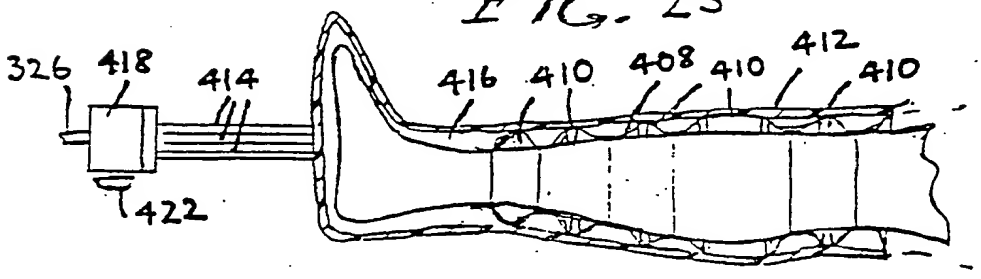


FIG. 23



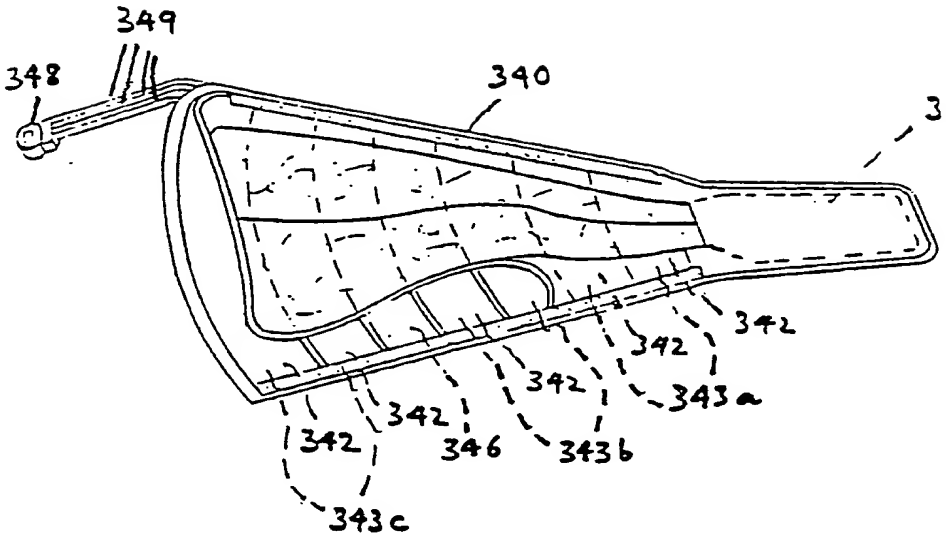


FIG. 16

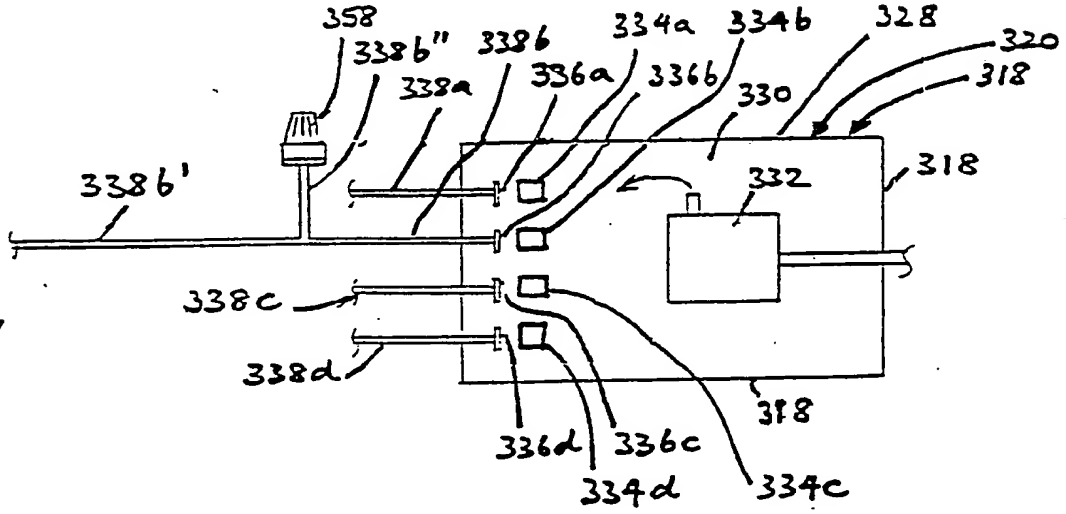
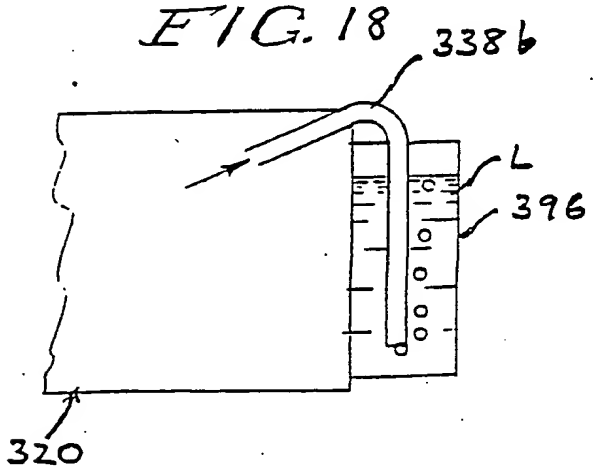


FIG. 17

FIG. 18



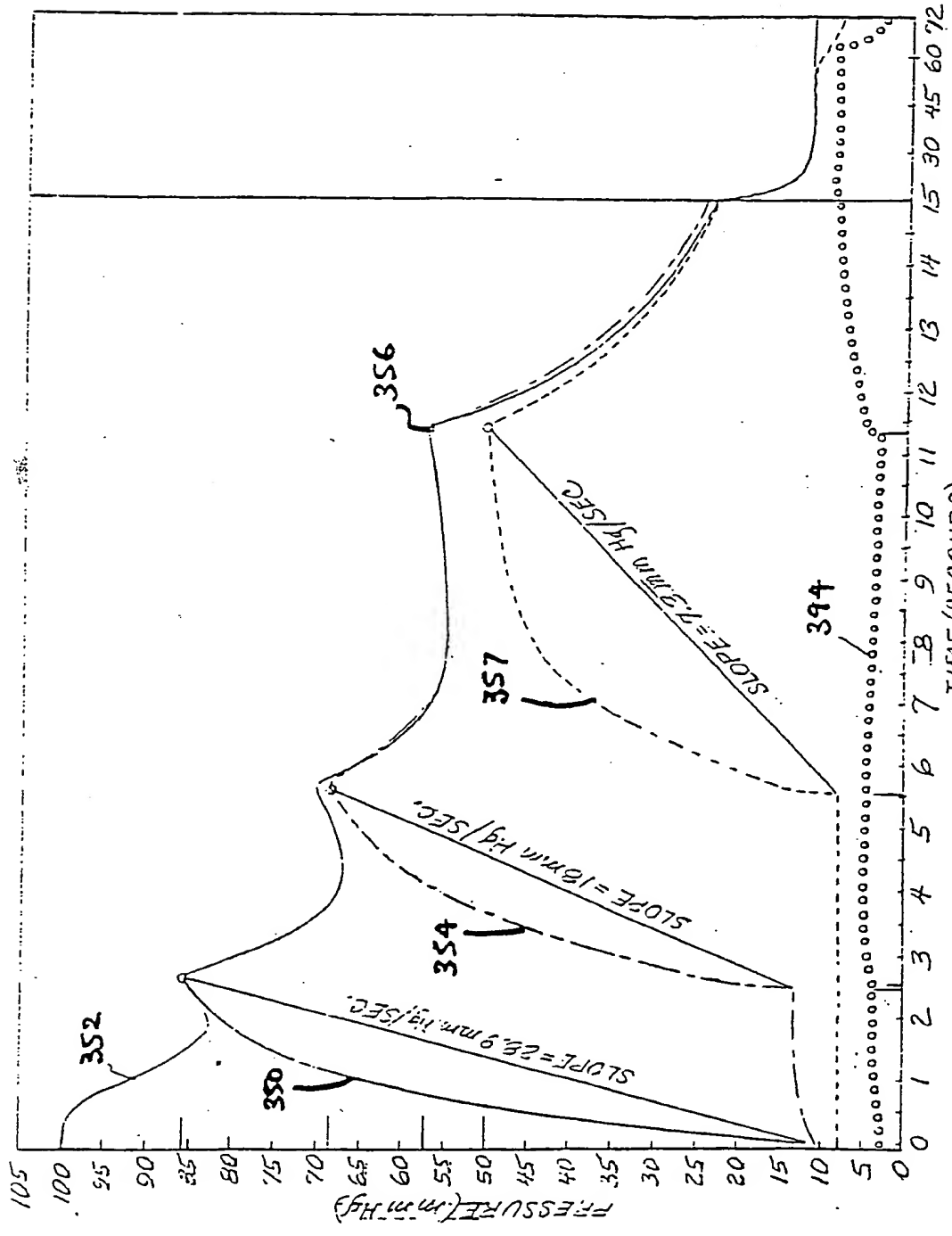
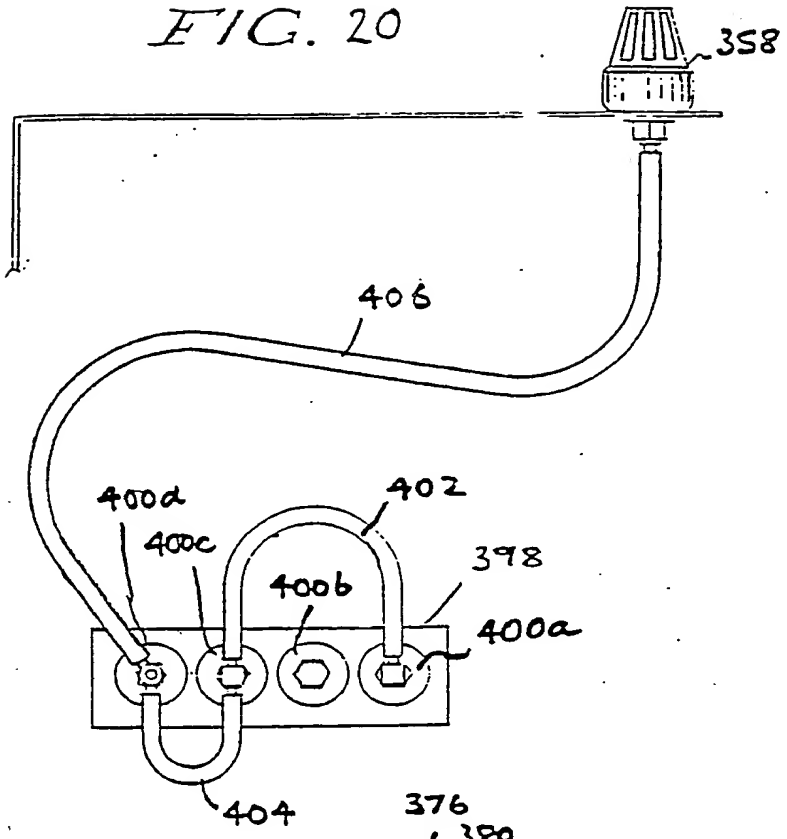

PRESSURE (mm Hg)
TIME (SECONDS)
352
350
354
357
356
394
SLOPE = 28.9 mm Hg/SEC.
SLOPE = 18mm Hg/SEC.
SLOPE = 7.2mm Hg/SEC.

FIG. 19

FIG. 20


358
406
400d
400c
402
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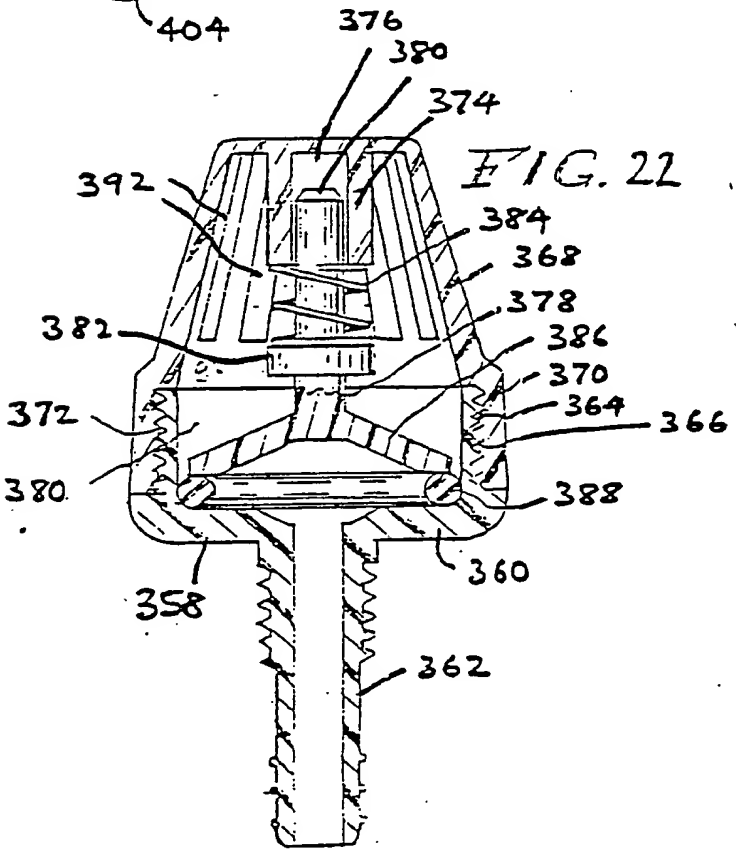
400b
400a
404

FIG. 21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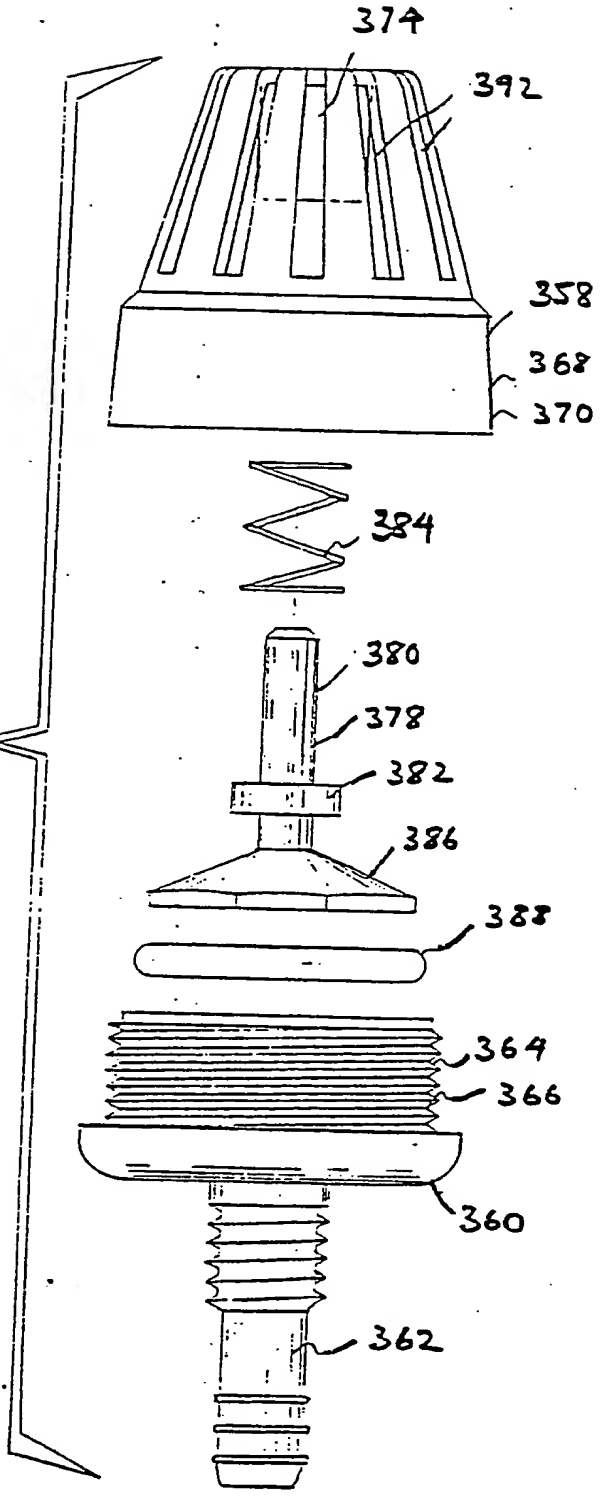

FIG. 21

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European Patent Office
Office européen des brevets

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(71) Applicant: THE KENDALL COMPANY
One Federal Street
Boston Massachusetts 02110-2003(US)

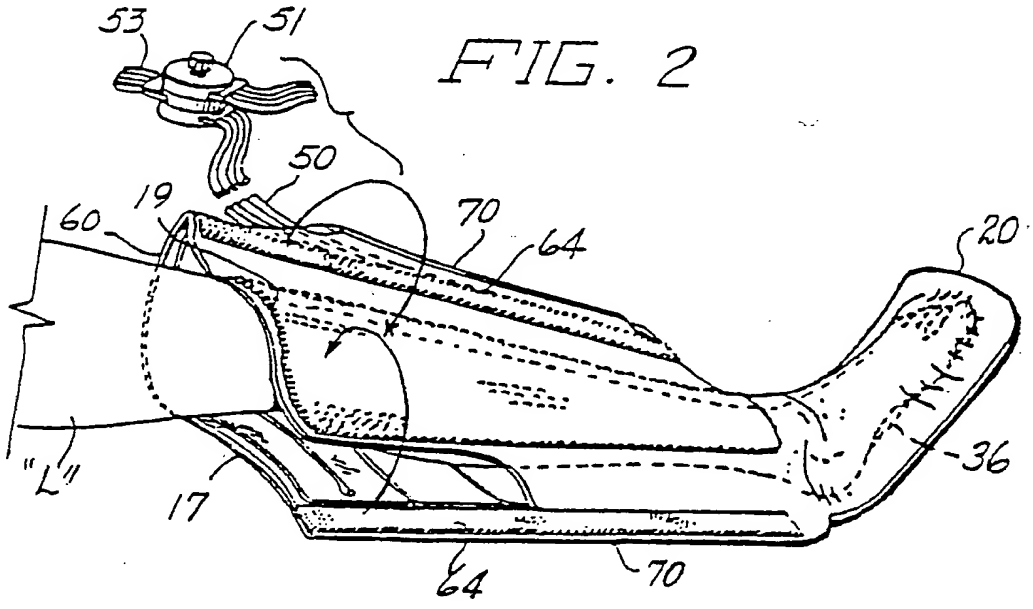
(72) Inventor: Dye, John F.
332 Vincent Place
Elgin, Illinois 60120(US)

(74) Representative: Kearney, Kevin David
Nicholas et al
KILBURN & STRODE 30 John Street
London, WC1N 2DD(GB)

(54) Full length compressible sleeve.

(57) A sleeve for applying compressive pressures against a patient's limb from a source of pressurized fluid, wherein the sleeve comprises a multi-layered sheath (10), having a proximal (60) and a distal end. Generally parallel side edges (52, 54) extend between the proximal (60) and distal ends, which side edges (52, 54), on the proximal half of the sheath, are adjustably wrappable about the patient's limb, once it is inserted in the sleeve (10).

FIG. 2



EP 0 388 200 A3

European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application number: EP 90 30 2781

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
X	US-A-4 029 087 (DYE et al.)		A 61 H 23/04
	* Figures 1,5; abstract *	1,5	
Y		2-4, 6-10	
	--		
Y	EP-A-0 168 085 (HULSBERGEN HENNING)		
	* Figure 1; page 4, lines 12-16, 31-32 *	2,3	
A		5	
	--		
Y	US-A-4 153 050 (BISHOP et al.)		
	* Figures 3-6; column 3, lines 30-54 *	4,7-9	
	--		TECHNICAL FIELDS SEARCHED (Int. Cl.4)
	./.		A 61 H

INCOMPLETE SEARCH

The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims.

Claims searched completely: 1-10,13

Claims searched incompletely:

Claims not searched: 11-12

Reason for the limitation of the search:

Method for treatment of the human or animal body by surgery or therapy (See art. 52(4) of the European Patent Convention)

Place of search	Date of completion of the search	Examiner
THE HAGUE	13-02-1991	JONES

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D : document cited in the application
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PARTIAL EUROPEAN SEARCH REPORT

Application number

EP 90 30 2781

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 4)
X	US-A-4 370 975 (WRIGHT) * Figure 1; column 1, lines 55-58 *	13	
Y		6	
	--		
Y	US-A-4 374 518 (VILLANUEVA) * Figures 1,2; column 3, lines 42-46 *	10	
	----		TECHNICAL FIELDS SEARCHED (Int. Cl. 4)